

SpeechVive - Deal Memo

Publication Date:

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# Introduction

**Purpose**

The purpose of this Deal Memo is to elaborate and summarize all due diligence and assessment efforts related to the investment suitability of the company in question. This Deal Memo is confidential and may contain proprietary information; nevertheless, it may be circulated to Southwest Angel Network Members not involved directly with the due diligence process, or with other Angel Networks for the purpose of deal syndication.

The Southwest Angel Network investors involved in the creation of this Deal Memo are attempting to confirm or deny statements or assumptions related to the team, technology, market, customers, vendors, intellectual property, competition, exit opportunities, deal terms, and any other key aspect critical to the proposed investment. Each area of due diligence will the summary of the interview or analysis.

After due diligence efforts are complete, those Southwest Angel Network Members involved with due diligence may articulate in their own words why they are investing based on the opportunities they see.

**Disclaimer**

This Deal Memo is in no way a recommendation to invest. The Southwest Angel Network does not make investment recommendations (yes or no) on any company that comes before the network. Each angel must make their own investment decision. The information and analysis found in this document are based on the best efforts of those involved while evaluating the company in question. It is incumbent on each potential investor to conduct his/her own assessment based on expertise or investment criteria. Angel investments are made on an individual basis, and at no time will an investor hold other investors responsible for investment decisions as a result of this Deal Memo.

**Process**

* 1. The deal lead anticipates making an investment unless the due diligence uncovers negative information.
  2. The deal lead is the primary point of contact with the company
  3. The deal lead has final editorial responsibility for all sections of the deal memo
  4. The deal lead recruits the deal memo team and Identifies a lead for each section of this document. Some team members may be responsible for more than one section.
  5. The deal lead asks the company to complete the Supplemental Information form.
  6. At the start of the deal memo process, the deal lead gets agreement with the section leads and the company on a date and time for a final call with the company.
  7. Each section lead reviews all available information and does any additional research deemed helpful, possibly including talking to experts, doing a web search and making reference calls
  8. The section leads write a first draft of their sections, develop a list of questions for the company (documented by the section lead in section 15) and any agreement needed to be reached with the company before funding (documented by the section lead in section 3). Unless you are making a number of phone calls to customers or for CEO reference checks, it is our expectation that you will spend no more than 2 hours to draft your section. If you don’t feel comfortable that you can complete a draft in that amount of time, please contact your deal lead.
  9. The deal lead can ask the section 15 questions of the company in real time (possibly including the section lead in a conference call with the company) or save the questions for the final conference call with the company.
  10. The final conference call is held with the company to review the contents of sections 15 and 3.
  11. The section leads then completes the write up of their section and assigns a score using the rating criteria defined in the Executive Summary, section 2.
  12. The deal lead writes section 2 (Executive Summary), deletes section 15, and makes any updates to any other sections as deemed appropriate.
  13. The Deal memo is circulated to all SWAN angels.

# Executive Summary

{Note: this Executive Summary narrative (top 2/3s of the next page) was shared with Steve Mogensen and he was asked to identify any misunderstandings on our part. He replied via email that we had no misunderstandings. Regarding the lower valuation cap, I had discussed in a call $5.5M. He replied in so many words that other angel networks don’t care about the social impact mission and that SpeechVive wasn’t showing a 10x return in 3 to 5 years. He gave the clear impression that he really wants (needs?) to close this deal with us]

**Social impact:** We believe that the product has high efficacy in terms of helping many Parkinson’s patients to resume effective verbal communication. This has been validated by one real-life, test-case involving a SWAN angel’s brother.

**Team:** We believe that the existing team is highly capable, although the new CFO (on board for 3 months) needs to become more plugged into how prior financial transactions have been recorded and are reported. We believe that from a cash flow point of view, prior finances are likely accurately recorded. The question is how the prior transactions have been reported on the income statement, balance sheet and the pitch deck.

The team is highly motivated and has been willing to work with no salary for some period of time. There is some risk of losing employees who are not being paid. Critical hires have not been made due to the shortage of funds. This includes a lead developer and a lead marketing person. The company needs to raise enough funds to support these hires. The hires will be critical to reducing cost of sales/increasing revenue and to delivering future-generation products.

**Business Risk:** A significant business risk is the current lack of a reimbursement code, although the company has stated that they are confident that a code will be issued in 2020. The failure to have a code established will likely negatively affect both future revenue and their exit potential

**Go to market:** We believe the go to market plan to be sound, achievable and well understood.

**Competitive positioning:** We believe that the product offers significant competitive advantages in terms of efficacy, and the company believes that they have adequate patent protection. Additional refinement of the product (Gen 2 and Gen 3) should increase both competitive advantages and market acceptance.

**Deal terms:** We believe that the requested $8M valuation cap is too high given the lack of an insurance reimbursement code. The company is open to discussing a lower number if we bring an interesting amount of investment dollars to the table.

As shown below, in each of the assessment areas, the company has been reviewed against applicable criteria and given a score using the following scale:

|  |  |
| --- | --- |
| Score | Score Description |
| 5 | Effective – Satisfies all criteria. |
| 4 | Sufficient – Meets most criteria. Needs some modifications. Not a barrier to funding |
| 3 | Needs Improvement – Meets a portion of the criteria. Needs work and additional capability, but the company appears able and committed to address the concerns both now and after funding. |
| 2 | Potentially Problematic – Fails to meet most criteria. Issues may be overcome, but it is likely that the company is not fundable at this time. |
| 1 | Critical – Fails to meet criteria. Issues cannot be overcome. Company should not be funded. |

The average of the scores below is 4.00 (yes, it just so happened to come out as a round number)

|  |  |  |
| --- | --- | --- |
| Assessment Area | Overall Score | Remaining Risks and Concerns |
| Social Impact | 5 | Easily identifiable impact. Scaling will increase this impact and the company leads with the impact angle. |
| Team and Operating Ability | 3 | Critical staff at risk of leaving due to no pay. No product development team, and no marketing personnel. No specific plan for hiring aa marketing resource. |
| Product and Technology | 4 | Solid product and technology with the only concern that there is currently no full-time developer on the team. |
| Market Size and Customer Problem Verification | 5 | Solidifying their Medicare position by October will be critical to bringing the price to a level with the majority of the available market. Functionality around hearing aids and add-on features, such as a small ear loop, to secure the device for sports will help expand their market potential. |
| Go to Market Strategy | 4 | They are following a well-worn path in medical device sales. There are concerns but they are early in the execution of the GTM plan. |
| Competition | 4 | In-ear device competition is very limited. Competitors efficacy in stuttering is questionable with no evidence of efficacy in PD. Speech therapy methods have long history and should be competitive target as well. Disrupting competitor “delivery models” may unlock more advantage. Cost reimbursement issues could impact competitiveness and scalability. |
| Exit Opportunity | 3.5 | ROI & acquisition potential could swing significantly: Medicare approval uncertain. The revenue ramp & the $$$ that need to be raised are probably optimistic, which is true for virtually every start-up. |
| Proposed Deal Terms | 3.5 | Proposed Cap of ~$8M too high. Recommend we propose Cap of $5.5M if SWAN invests at least $100K. If lowered, would raise deal-term rating to 4.5 |
| Corporate Structure and Governance | 5 | No concerns |
| Finances | 3 | Based upon possible improvement in CFO who has only been on board for 3 months. |

# Agreements that need to be reached with the company before funding

Identify any agreements that need to be reached with the company before angels invest.

* Pre-money / valuation cap.

# **Social Impact – Score**: 5

**Section Lead(s): Suresh Sundarababu**

**Impact Metric(s) for quarterly reports to SWAN:**

Note that as part of the application process the company pledged to “Provide a quarterly social-impact measurement report using a mutually agreed to impact metric.” Here are the metrics proposed by the company :

* Number of total patients receiving a SpeechVive device
  + Number of patients receiving a SpeechVive through the VA
  + Number of patients receiving a SpeechVive through Medicare
  + Number of patients receiving a SpeechVive through Commercial insurance providers
* Number of total patient/caregiver events attended by SpeechVive (Victory Summit, support groups, etc.)
* Number of total SpeechVive devices programmed via telemedicine platform
  + Reduced burden of travel for patients and family members
  + Reduced carbon footprint for speech therapy which requires 16 one hour sessions over 4 weeks

**Summary**

Speech Vive fundamentally exists to make the quality of life better for those with Parkinson’s disease. Their technology specifically targets to improve their ability to communicate and thus enhance the quality of life.

Speech Vive can demonstrate with data, although it is a small set right now, that they are able to provide improved ability to communicate. This is an application that almost everyone can see the impact and the benefit. The social impact angle is very prominent in their pitch and in their website and collaterals.

Angel Bob Glowienke has his brother, a long-term Parkinson’s patient, try the device and the device was extremely effective, leaving family members overjoyed.

The measurement of benefit seems simple as well. The more reach they have, higher the impact.

# Team and Operating Ability – Score: 3

**Section Lead(s): John Soyring**

The process I used was to talk one-on-one with each of the SpeechVive leaders named by Steve Mogensen. Part way through the due diligence work, Steve suggested I also talk with the board members, which I also did with one-on-one telephone calls. Each call lasted 60-90 minutes and covered a wide range of leadership competencies pertinent to the individuals’ roles.

I also did internet searches for other sources of information about each individual.

I rated the team as a **3** for three primary reasons:

1. The position for doing the **product development and testing** work was open during my due diligence. The original development & testing work had been done by Brent Knecht and board member Sean Connell (on a part-time basis). Sean is willing to do follow-on work for the Gen 2 and Gen 3 product releases, but an agreement is not in place. Steve Mogensen claims that Brent is willing to return to do work with SpeechVive, but I know Brent also works at Allegion. The work needed be done is to secure work contracts with Brent and Sean (and possibly more) to do the development and testing work for these next two product releases is a key risk that needs to be mitigated.

2. The current staff of SpeechVive are all essential, and fortunately all have extensive work in the specific professional domains of their jobs. The risk is that several of these people are in positions critical to the success of the company and, as such, the **retention** of these people is key to enabling the company to achieve its business objectives. A factor that creates even greater risk of losing a person is that these people have been working without income for months to years. I tested each one on retention … especially digging in on whether they each had the financial resources for their families to continue working for SpeechVive. I’m satisfied that each has the financial resources to keep working … and that they have a personal (emotional) commitment making the SpeechVive product a market success … and delivering value to people who live with Parkinson’s Disease. Retention of these key individuals is a business risk for which investors need to be aware.

The people most critical to retain are Jessica Huber (to give credibility to the product); Ashleigh Lambert (the SpeechVive device cannot be successfully adapted to each person/patient without the tuning work that Ashleigh does one-on-one with each product user); Price Cleaver (he’s been selling to the same neurologists and speech therapists for the past quarter century); and John Ridge (he has the deep skills and experience to get Medicaid codes in place in order to greatly facilitate payments to SpeechVive.) The loss of any of these people will damage SpeechVive’s ability to reach its financial plan objectives.

3. The company does not have a person identified to make **marketing** decisions and there is not a marketing plan in place. Using social media for earned advertising rather than paid advertising is what the company needs to do. Without adding a formal social media marketing focus, sales will continue to be primarily based on making cold calls on neurologists and speech therapists.

**Steve Mogensen, President, CEO, & Co-Founder**

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[linkedin.com/in/steve-mogensen-4946a16](http://linkedin.com/in/steve-mogensen-4946a16)

"Steve has over 25 years of experience in the medical device industry, specifically in sales, marketing, operations, M&A. He was part of the management team at MedSource Technologies which took MedSource public in March, 2002 and a senior executive at Enpath Medical when the company was sold to Greatbatch in June, 2007 for $103M. Steve was the Managing Director and integral in starting a biotech incubator at Purdue University in 2008 where he discovered the SpeechVive device. He worked with the University to license the technology in January 2013 and co-founded SpeechVive, Inc. with his co-founder and inventor Dr. Jessica Huber."

**Dr. Jessica Huber, Ph.D., Chief Scientific Officer, Inventor, & C0-Founder**

+1

[jhuber@speechvive.com](mailto:jhuber@speechvive.com)

<https://www.purdue.edu/hhs/news/2019/05/jessica-huber-named-associate-dean-for-research/>

"Jessica is a professor in the Speech, Language & Hearing Sciences department and the Interim Associate Vice Provost for Faculty Affairs at Purdue University. Dr. Huber serves as the Chief Scientific Officer and continues to remain actively involved in the research of SpeechVive, publications on SpeechVive, and is a board member. Dr. Huber has been actively involved in Parkinson’s research for over 15 years."

**Ashleigh Lambert, M.S., CCC-SLP, Director of Clinical Marketing**

[alambert@speechvive.com](mailto:alambert@speechvive.com)

<https://www.linkedin.com/in/ashleigh-lambert-2186025b/>

"Ashleigh has over 12 years of experience as a speech language pathologist and working with people with Parkinson’s disease. She is instrumental in the sales, marketing, training, and exceptional clinical support for SpeechVive. Ashleigh handles all patient facing activities including programming devices for patients via the SpeechVive telemedicine platform."

**Price Cleaver, Vice President Sales**

**+1**

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"Price joined SpeechVive in May 2018. He has 25 years of experience at Medtronic in the deep brain stimulation division. He brings a wealth of knowledge in the Parkinson’s space and more importantly relationships cultivate throughout his career with movement disorder neurologists (MDS). The MDS physicians are key to penetrating the Parkinson’s market and Price has established a beta territory in Texas where we have significant MDS support since Price’s hiring."

**John Ridge, Vice President Reimbursement and Managed Care**

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"John brings 2 decades of experience working with startup companies to develop reimbursement strategies which impact successfully driving revenue. John joined SpeechVive in November 2018 and quickly developed and implemented a reimbursement strategy which has quickly gained traction with both Medicare and commercial insurance companies."

**Brent Knecht, E.E.**

[**https://www.linkedin.com/in/brent-knecht-84636b119/**](https://www.linkedin.com/in/brent-knecht-84636b119/)

"Brent is the Engineering Manager at SpeechVive. Brent has over 20 years of experience with firmware, hardware, and software in electro-mechanical devices. He has been instrumental in the transfer from “development to manufacturing” of SpeechVive and continues to make improvements in manufacturing and managing the contract manufacturer relationship. Brent has led the manufacturing process improvement resulting in a 99%+ acceptance rate and reducing COGS by 10%."

**Nora Doherty, temporary Board member**

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Additional Staffing information from Speech Vive after asking about lack of dedicated staffing:

We are concerned about lack of dedicated staffing on marketing and on gen2/3 development. What are your plans to address this? At what point in time do you plan to make those hires?

 We have hired a full-time Operations Manager with 20 years’ experience in the industry, Michelle Smith. The title may throw you off but as you know in a startup you have to wear many hats. Michelle is working with Ashleigh on a number of initiatives and one of them is our patient facing marketing program.  Michelle worked part-time in November/December as a trial run and joined the team full-time January 1st.

We have also engaged Sean Connell (current SpeechVive board member) Purdue Biomedical Engineer PhD, Northwestern MBA, and did early work on the SpeechVive device. Sean will be leading the engineering effort to reduce COGS and the Gen II/III devices. The project(s) for all intents and purposes are one.  Our first objective is to go from analog circuitry to digital. This will be our most significant opportunity to: reduce COGS, reduce labor required for assembly, and reduce footprint (overall size of device).  We have already made significant progress on this project. We are currently building 10 digital prototypes which we will then test and compare to analog performance to ensure device stability and performance. We expect to complete the build and testing in the next 60 days. We are also incorporating the “auto-programming” feature in these prototypes which will be a significant improvement to our overall strategy by not having to program each device for each patient. Again, the prototypes are incorporating this technology as well.

Right now, we are engaging Sean on a project basis and paying him hourly. Ultimately, we would like to bring him on board full-time and will most likely do that mid-summer this year if we have the appropriate funding.

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# Product and Technology – Score 4

**Section Lead(s): Robert Canik and Jeff Toler**

The Speech Vive product was beta tested with VA medical centers in 2015 and has been shipping the first generation of the product since January 2017. They have shipped a total of 342 units and have a historic return of 3% so the product is very mature and stable. They have been working with their contract manufacturer (Engineered Medical Systems) since 2014 and have developed 6 plastic injection molding tools that will enable quickly ramping up to as many as 6000 devices per month and also reduce labor cost by moving manufacturing to Malaysia (current COGs is $736 but have a plan to get it to under $500 long-term). The current design has 3 PCBs in it which appears to me to be excessive, but they are currently planning to reduce that to two PCBs in the next generation of the product which should reduce the COGs even further below $500. They already have CE certification in the US and Canada and from my own experience it is very straight forward to file with different agencies to get certified throughout the rest of the world. They have roadmap plans for follow-on products. Specifically, a Gen II version that allows the user to self-tune it and a Gen III that will be smaller allowing the user to more easily put the device on themselves. They have two patents on the product that should discourage competitors.

My biggest concern is they lack having a dedicated engineering team. The person that designed the product no longer works for Speech Vive since they quit paying salaries in January 2019 and has a full-time job elsewhere. I think if we invest, we need to make it under the condition that they retain him at least on a part-time basis as this will accelerate the development of Gen II and Gen III and also help reduce the GOGs.

Additional information from Bob Glowienke with his assessment of the product:

Here is my firsthand account of the use of the SpeechVive device my brother (Ken) agreed to test.  A bit of background, Ken was diagnosed at 37 with early onset Parkinson (PD).  He is now 54.   He has had 5 Deep Brain Stimulation(DBS) procedures and has been at the forefront of tech and meds to help him with the ever worsening symptoms of PD. His ability to communicate effectively is one of those.

Today he went through the normal video conference based  turn up and tuning exercise as described by SpeechVive.  Ashley Lambert,, their VP of Clinical Development, was driving the session and walked him through a mapping exercise of his voice so she could tune the device in real time.  Once done with the mapping she had him put the device on and then mapped his voice again using the USB attached microphone included in the kit.   Immediately he picked up a 40% increase in the volume of his voice.  This entire exercise was under 20 minutes to complete.

Myself and his wife were both there as he went through the process.   The change in volume and clarity of his speaking voice was definitely noticeable to us both right away.  I stayed with him for an hour after just chatting and I did not need to once ask him to repeat himself and neither did his wife.  This is something we have been doing constantly for a few years now.  While I can not speak to the long term efficacy of the device I can tell you it worked as advertised.

Quick side note, Ashley was fantastic.  As an investor I strongly hope she is long term committed, she was that good and made the experience very enjoyable and effective for Ken.  I am investing.

Additional Information from Speech Vive below:

1. Cumulative units sold since inception?

341

1. Cumulative units still in use today?

 We are unable to track this today due to HIPAA restrictions. Gen II will have a Wi-Fi enable charging station which will transmit user data to the cloud. We will track total users as well as total talk time each day by each patient. We have a few other things we are considering as well.

 Overall return rate 13/341 is 3.8%.  Most of these devices were early devices. The return rate for the last 2 years is 2.7% and the return rate in 2019 was 1.27%. Certainly a great trend.

1. Units sold in 2017, 2018, and 2019 (detailed by year)?

2019 = 80

2018 = 109

2017 = 80

1. Do you have plans to support MacOS and if so when? We currently use both Mac OS and Windows for programming devices. The diagnostic app we developed is Mac based and available for free in the App store.

  I (Steve from Speech Vive) would also like to add a couple of points.

* 1. Q4 2019 was our best quarter ever at $85,984 which is a 9% improvement over our prior best quarter (Q1 2018) $78,710.  While this is good news, the better news is we know “why” and we are adding resources to replicate these efforts.
  2. Beginning in 2019 our VA revenue in TX was 5% of our total VA revenue through 1 VA in Dallas. Our VP of sales started covering TX and by the end of 2019, 60% of our VA revenue came from 5 VA medical centers in TX (Dallas, Houston, San Antonio, Austin, Temple). A consistent sales presence drives revenue.
  3. Our 2nd sales rep started this week and will be covering the west coast. We are currently interviewing a candidate to cover Florida and a 4th rep for the NE US.
  4. Our HCPCS code application has been submitted and received by Medicare. We are confident SpeechVive will receive a code which will take effect 10/1/20.
  5. We are building the infrastructure today which will allow us to ramp up filing Medicare claims to be ready for the influx of orders we will receive in October.
  6. We have a robust COGS reduction project this year and have very aggressive COGS reduction targets to meet during the year.

# Market Size and Customer Problem Verification - Score: 5

**Section Lead(s): Elizabeth Jennings**

For this product, the addressable market of Parkinson’s patients is currently limited by the price point: without reimbursement, the product is out of the grasp of many fixed-income patients who are already experiencing increased expenses for other treatments. While reimbursement is underway, it’s crucial in making the product accessible to a significant portion of the Parkinson’s population. According to an NIH analysis (1) from 2013 (using 2010 dollars), the additional financial burden on a new Parkinson’s patient in the year after diagnosis—without any other complications—was $4,072. This rises sharply as the disease progresses; those requiring ambulatory devices found themselves burdened with $26,467 in annual costs and those requiring institutionalization faced $37,410 in expenses. Excess indirect costs came to a mean of $3,111 in the year after diagnosis. While commercial insurance may cover a large portion of those costs, standard Medicare may not cover all. Because their target market is already financially strained, ensuring that they continue to fortify their payment options is crucial. (As an aside, it is estimated that the economic burden of PD in the US is $51.9B) (4).

Excluding financial limitations and accepting that the average age of Parkinson’s diagnosis is 56 (only 4% are diagnosed before 50), the potential market is substantial and growing as the US population shifts upward in age (2). The Parkinson’s Foundation estimates that in 2020 there are 930,000 PD patients in the US, growing to 1.2 million by 2030. 52,500 of those live in Texas, one of the largest PD populations in the US. The Foundation estimates that this number has doubled since 1978. Men are more likely to have PD than women, though age is a bigger factor (3).

Beyond the financial burden and hassle of dealing with insurance, the next important limiting factor in market penetration is that patients who use hearing aids cannot also use this device simultaneously. According to the NIH, 8.5% of Americans aged 55-65 has disabling levels of hearing loss, rising to 50% of those who are 75 or older (5). So while the ideal customer at the moment is a financially secure male in their 60s-80s who does not rely on hearing aids, compatibility with hearing aids—at least some of the more modern types that do not have hardware behind the ear—will be essential in increasing their market. (It is worth noting that I am not absolutely certain of the limitations of use with hearing aids, so it is possible that not all versions of hearing aids are incompatible).

In terms of market accessibility, their relationships with the VA will be critical—beyond word of mouth, customers reported hearing about the device via the VA as an important factor in getting the device (even though they then had to educate their primary physician, not at the VA, in order to receive it). The limited conversations with customers corroborate Victor’s and Bob’s findings that partnerships with support organizations and social media will be useful in expanding their market reach and should not be underestimated.

As is the tendency with innovation in healthcare, the primary market driver has been leaps forward in technology catalyzed by the fervor of a population that has no other recourse for a comparable solution. There aren’t many medical devices designed around improving the speech of PD (or stroke, etc.) patients, as limited by our understanding of the progression of the disease and the ability to miniaturize hardware (until recent decades). As the main competitor is actually speech therapy—other devices are not one-to-one solutions for the actual causes and manifestation of symptoms that Parkinson’s patients experience—the biggest lag will be simply awareness: patients and providers alike need to be informed that this device exists. Literature surrounding how to obtain it and onboarding patients needs to be clear and abundant.

Three customers were interviewed. Notable findings:

* Patients using the device all mentioned independently that the device is as much for the caregiver as it is for them.
* When speaking with one couple—Barbara and Paul Schneider—I noticed that Paul’s PD was significant, yet he was able to lead the conversation with strength in his voice.
* All patients mentioned how frustrating it is to have to repeat themselves and that this device greatly improved their experience in conversation, socialization, and self-esteem.
* Barbara in particular emphasized how important the device has been in Paul’s life, saying that as an intelligent person with a lot to bring to conversation, living without the device made him feel isolated and overlooked—whereas he had built his life on being a very engaging and contributing social person. She felt it was valuable against depression for that reason.
* The biggest concern expressed by customers is that they’re scared they’ll lose it, particularly when exercising either at the gym or when playing a sport. Steve has created a small semi-flexible loop that fits in the ear to help hold it secure, but they’re still generally concerned about it flying out and getting damaged or lost. Caregivers expressed concern that the device could be lost simply out of misplacing it, as it’s quite small.
* All customers said that they would use the device for the rest of their lives. All customers felt like it helped them speak more clearly and louder than speech therapy did.
* Paul Schneider was a part of the early trial at Purdue (alongside another interviewee, Terri Weymouth) and mentioned that he was heartbroken when he had to give the device back at the conclusion of the trial. Barbara said that the improvement in his voice lasted for several weeks before it declined and returned to its previously poor levels.
* All customers said that the device was fairly easy to use and to get accustomed to, and that the SpeechVive team was exceedingly helpful and accessible. No one complained that the initial programming was a burden.
* Regarding ease of use, Paul Schneider pointed out that it was actually trickier to place the device that you might think: users have to do that themselves and they tend to have fairly trembling hands. But he said he was able to get the hang of it. No one complained about difficulty in placing the device.
* Paul Schneider told an anecdote: he was with his Parkinson’s boxing club and showed it to his team. They were all amazed and immediately wanted one, until they heard how much it cost. Many lost interested then, but expressed envy over it. I’m not sure if Paul let them know there are insurance options.
* On suggestions for improvement, the most common request was for the ear loop and a small carrying case to be included with the device (so that it doesn’t get lost, either during sports or misplaced). Other requested further miniaturization and style improvements, for the more fashion-conscious ladies.
* All customers reported having told anyone who was interested about the product. I believe word-of-mouth will be the foundation for growing this product from the patient-up, as news will spread from support groups faster than via physicians.
* No customers were concerned about the cost: they could all afford it and were very pleased with the value of it. Because its benefits are largely intangible, no one was concerned with ROI.
* No customers mentioned any issues with reliability with the product, and all said they had been able to contact either Steve or Ashley via email or phone with ease and quick responses.

In essence, we’re looking at a large, stable, growing target market that is financially vulnerable but desperate for this product and willing to go to great lengths to acquire it. It is my belief upon reviewing the state of the market environment and speaking with customers that product-market fit has been achieved, there is a substantial-to-dire need for this product, and that the opportunity to fill that need will continue to grow for at least the next decade (and likely beyond).

1- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3757266/>

2- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4831034/>

3- <https://www.parkinson.org/Understanding-Parkinsons/Statistics>

4- <https://www.parkinson.org/blog/research/economic-burden-study>

5- https://www.nidcd.nih.gov/health/statistics/quick-statistics-hearing

# Go to Market Strategy- Score: 4

**Section Lead(s): Victor Mieres, Bob Glowienke**

Below are some of the key points around SpeechVive’s GTM plan. We believe the plan to be sound, achievable and well understood. Given where they are in the plan and it’s execution they have earned a score of 4 from our due diligence.

* SpeechVive is following a well thought out, scalable, medical device industry proven sales model and marketing plan.
  + Current sales force is 2
  + 1-2 additional sales heads in H1 2020
  + 3 additional sales heads in Q4/Q1 of 2020 are planned once they have secured their Medicare HCPCS code for billing.
* Their sales efforts in North America are targeted at:
  + Veterans Admin,
  + Movement Disorder (MD) clinics physicians and speech therapists
  + Direct contact from potential PD patients.
  + International presence in the future through distribution channels yet to be pursued.
* At present 80% of revenue comes from the VA and 20% comes from direct pay PD patients. While they will continue to grow all of their target segments their go forward plan drives much of their growth to come from MD clinics referrals/scripts for the device.
* Sales leadership has a track record of success selling to MD Clinics.
* Marketing efforts currently have been focused on education to and through many of the known organizations in the area like the MJ Fox Foundation, Parkinson Foundation etc. This has been great exposure so far and will continue. Social medial looks to play a significant role in their efforts post funding as well as a handful of targeted industry events catering to the VA and Movement Disorder clinics.
* Ultimately, to achieve their growth targets SpeechVive MUST secure the necessary Medicare HCPCS billing code to be able to be able to submit and secure payments on the device. Currently they are billing under a Medicare E1399 code but have applied for their own HCPCS code. It has already been applied for and they have a target for it to take effect of Oct 1, 2020. This is key to their plan and looks to be on track at time of this writing.
* Ongoing concerns:
  + Staffing according to plan is a small concern. SpeechVive will be hiring sales people initially on a commission only basis and move reps to a salary/commission model as the business grows. Hiring the right personnel under this plan carries some concern/risk.
  + Ongoing success in the MD clinics. While this path is understood, execution/progress will need to be closely watched.
  + Securing the Medicare HCPCS code for billing is central to their success. Need to track progress.
  + Minor concern is how they operationalize their sales and marketing motion/tools once growth begins to accelerate.

# Competition – Score: 4

**Section Lead(s): Mark Cirinna**

Competition in this space falls into a few key groups -

1. Apps and online tools
2. Speech Therapy (LSVT most widely recognized method)
3. “Computer” devices that generate speech for the user (e.g. - Lingraphica)
4. In-Ear devices that create new speech behaviors

Apps and online tools are very low cost, easily accessible, and user paced / dependent. Other than various reviews there is no concrete data on efficacy. There will always be a market for these especially with cost sensitive users and they will constantly evolve as handheld devices evolve.

“Computer” devices that generate speech are a proven option for those who have lost or have severely compromised speech. They required the use of a “notebook or pad” device and user inputs/selections to function. While they are effective they lack ease of use and are somewhat intrusive to a conversation process.

SpeechVive self-identified their competition to be the 2 other in-ear device providers – Speech Easy and Small Talk.

Speech Easy and Small Talk were initially focused on individuals who stutter and utilize an audio technology – Delayed Audio Feedback and Frequency Altered Feedback to improve speech and volume for the patient. User reviews are mixed on the efficacy of these solutions – with many reporting unsatisfactory performance. One actual study indicated that the effects of DAF / FAF are short term and lose effectiveness over time. All feedback that was found referenced only patients with stuttering issues. Was unable to find any relevant information regarding Parkinson’s patients. Appears that both companies “expanded” their marketing to address Parkinson’s patients as a natural extension of their technology – but without clear efficacy studies or data other than some anecdotal user reviews that are very limited. Speech Easy indicates they have thousands of users (one reference indicated 11,000 existing customers) - but sales data is not clear on either company from open sources. SpeechVive utilizes a different audio method referred to as the Lombard effect – they claim this approach is their key differentiator and competitive advantage. They have limited studies showing it’s efficacy but do not appear to have a significant volume user base to verify real world benefits over extended periods.

Speech Easy has 4 different form factors which gives them some advantage for users that prefer a small (hearing aid-like) in-canal solution to a larger behind the ear product. However, the behind-the-ear product can be easier to handle for those with Parkinson’s motor control symptoms.

Small Talk provides 3 different third party products (headphones, behind the hear, in-ear) with their solution – this allows the user to choose the interface based on varying usage modes. However, this does not reduce the cost of the offering.

Although they discount it’s effectiveness, SpeechVive’s own inventor has indicated in interviews that the most predominant method for addressing Parkinson’s speech issues is Certified Speech Therapy – specifically the LSVT method. This method has proven efficacy and results and is likely the accepted performance standard to compete against. Speech therapy is intensive, time consuming, and requires direct support of a speech therapist. SpeechVive technology could be a disrupter to LSVT over time and they should target this in their marketing and comparisons. LSVT is insurance and Medicare reimbursable in most cases with therapy related coverage.

SpeechVive’s pricing is comparable to other in-ear device providers – although they identify Speech Easy as having a $4500 price point – could not verify but Speech Easy has an entry point price of $2500 which may be for their similar form factor.

Pricing is not transparent for any of these solutions due to the complex network of providers you are directed to and left to work out specific pricing for your individual situation. Simplification of “delivery” here can become a major advantage if achieved.

If SpeechVive can address clean cost reimbursement, simplicity and cost vs. LSVT, efficacy over longer term and larger sample of patients (thousands vs. hundreds), and possibly direct purchase / ease of use (with minimal need for Speech therapist to guide and adjust settings) – they could establish market leadership in this space. Competitive response could be blocked by their IP which addresses the use of the Lombard effect for their solution.

Open questions –

1. Consider testing this technology for stuttering as this provides a market extension and larger opportunity.
2. Address why haven’t they gotten more traction in this space after so many years and what appears to be a superior technology.
3. Solve insurance and Medicare reimbursement issues or this would be a competitive disadvantage.

# Exit Opportunity – Score: 3.5

**Section Lead(s): Thorsten Mayer (TM), Co-lead Stephen G. Maysonave (SGM)**

**Sources:**

1. <https://www.medicaldevice-network.com/deals-analysis/medical-industry-devices-ma-deals-in-january-2019/>
2. <https://www.medworldadvisors.com/single-post/2019/03/07/Analysis-MedDevices-MA-Transactions-2018>
3. <https://mercercapital.com/assets/Mercer-Capital-Value-Focus-Medical-Device-18Q1.pdf>

**Is there a plausible exit?**

* + Significant M&A activities by leading medical device manufacturers in the past years (several billion dollars in the US only).
  + Valuation varies quite a bit (~5x on Revenue and/or ~10-30x on EBITDA). The valuation will usually be made based upon profitability, proven technology, significant enough customer base and potential market opportunity.
  + M&A deal sizes have been varying greatly (10s of millions to low single-digit billions).
  + **SGM:** Yes, Medical Equipment Suppliers, probably ~ companies with existing interests in the neurological space.

**Are there comparable exits in this industry?**

* + **SGM:** Medical equipment industry frequently acquires, however, no apparent proxy for this type of niche medical device.
  + Closest comparison to medical equipment M&As (reference #3)

**Is the company engaged with potential acquirers?**

* + No, not yet. From initial conversations with one of the major players in the space, likely Exit will be in the 2021/2022 timeframe, once uptake and product utilization hasbeen established (commentary from SpeechVive).
  + TM: I do believe that the timeframe is too optimistic. They’ll need to achieve a certain traction and validate that there is a large enough market. I would rather say 2022 to 2023.

**Is there a strategic investor and how does that enhance or limit exit options?**

* + Current investors would not be potential acquirers.
  + SpeechVive” “We will, however, consider approaching strategic investors in the space for potential future funding needs “. In other words when SpeechVive has been able to **validate the value** proposition and has reached a representative number of customers to credibly approach potential future acquirers. Probably around 2020 to 2021.

**Who are potential acquirers / what are the most likely exits and in what timeframe?**

* + **SGM:** Medtronic (has acquired ~60 companies), St. Jude Medical, Boston Scientific & others with existing interests / products in the neurological space.
  + **SGM:** For SpeechVive to be an interesting acquisition for larger medical equipment manufacturers, I believe their revenues need to be ~$50M, growing at least 50% per year, and with a quantifiable, easily accessible market opportunity of at least $500M.
  + According to Mercer Capital, deal valuations have ranged between 10 and 30x of EBITDA or ~3-5x of Revenue. I still struggle somewhat with the P&D forecast as it seems very optimistic regarding OPEX and consequently Operating Margin.
  + In the best-case scenario (Medicare code granted, achieve revenue forecast and average industry multiple at exit, not more than one more finding round) the ROI for us investors could be substantial (>>25x). That said, there are too many IFs. I still believe that their P&L forecast is too optimistic as far as OPEX and consequently Operating Profit is concerned. Hence, I rate them 3.5.

# SDEAL Terms – SCORE 3.5 (would raise to 4.5 if CAP lowered)

**Section Lead(s): Stephen G. Maysonave (SGM)**

**SGM Comments:** proposed Cap of ~$8M too high. **Recommend we propose Cap of $5.5M if SWAN invests at least $100K. If done, would raise rating to 4.5**

* **Proposed Terms:** 20% discount, 10% interest, conversion on minimum $1.5M equity raise, with an $8M cap
  + Need a copy of the proposed investment agreement
  + Need to clarify “what” the investment converts to and if it automatically does when $1.5M is raised in this investment vehicle
* **Cap:** believe that it should be lower based on:
  + SpeechVive Shareholder Communication of March 2019 states they have unsuccessfully tried for 12 months to raise $2.5M
  + Revenue decline from 2018 to 2019,
  + Series A post-money in 2016 at $4M,
  + Risk related to Medicare HCPCS code being granted
  + Believe their revenue ramp-up forecast is too optimistic
  + Believe they will need to raise at least $5-7M, probably more to properly ramp up sales, development, and claims processing after receipt of HCPCS code, especially if it is delayed

Additional Information from Speech Vive after we expressed concerns about the cap:

- The $8M cap feels a little high to us. We are considering proposing a lower cap if we can get enough investment dollars soft circled. Would proposing a lower cap be a non-starter?

 We understand your concerns and are open to your thoughts on where you see the value of SpeechVive.  Certainly NOT an non-starter.

If we invest we would like to have a SWAN member be on your board of advisors - are you open to that idea?

Absolutely. SWAN may have an ex officio position on the board. Depending on level of investment and desire, we could also discuss a board seat.https://ssl.gstatic.com/ui/v1/icons/mail/images/cleardot.gif

# Corporate Structure and Governance -Score: 5

**Section Lead(s): Bob Bridge**

The company is an Indiana C-Corp.

The company has a five-person board including two company reps, two investor reps and an independent member; nice!

The option pool is currently of acceptable size.

# Finances – Score: 3

**Section Lead(s): Wade Monroe and Bob Bridge**

**Summary:** Bob and Wade had a call with Steve Mogensen and their CFO Brain Kopp and pressed them hard on how they had stated finances in the pitch deck. The pitch deck financials do not always reflect GAAP principles. For example, in the pitch deck Steve had categorized sizeable non-dilutive funding as investments. While those grants were incoming cash that supported company operations just as an investment would, they are not technically investments. The total amount of cash previously received by the company appears to be reasonably accurately stated by Steve.

**Bob’s Perspective (score of 3):**

Brian immediately and fully understood the concerns we raised. Brian has been at the company only a few months and likely had not authored the pitch deck slide on finances. In Bob’s opinion, Brian is a highly experienced, capable and knowledgeable CFO )one of the stronger CFOs that SWAN has seen)., and believes that questions on the pitch deck reflect Steve’s CEO communication style which is to focus on the high-level story and not making his primary focus GAAP accounting accuracy. Brian needs to make sure the pitch deck finances are more accurately stated, and Bob believes that after our aggressive grilling on the phone that Brian will indeed do that.

**Wade’s Perspective (score of 3):**

The Deal Pitch indicates a total of $6.3 Million invested. However, only $2.2 Million is on the Balance Sheet. Brian, send Wade a list of the $6.3 Million. The investment list included a list of sources providing mostly services provided by Purdue University & NIH divided between Direct Costs & Total Costs.

The direct costs added up to $4,493,000 & the Total Cost sum was $5,703,000 (including the Direct Cost.) -Both the direct & total costs were included the “actual cash invested” in the company.

However, the Purdue University investment of at least $540,000 was doubled up in both.

Dilutive & Non-Dilutive Investment. Wade is not sure if Purdue actually invested $450,000 in cash as it may have been services

Included in the 2018 Revenue was a grant of $200,000. This should have been recorded in Other Income-very elementary. Also, SLP Kits are show as Fixed Assets. These are shipped out with the Product & should be Expensed.

In November, Wade saw a Forecast showing Revenue the year of about $494,000. The actual year end Revenue was $202,000-Very poor forecasting.

A competent CFO should never send out Financials with about 40% of the Revenue in 2018 misstated. The other errors found were smaller but should have never been published in Financials sent to potential investors.

Major decrease in Revenue in 2019 vs 2018. We received explanation of not having Sales Resources to make Sales. Problem may be deeper - need check out the quality of Product & Competition by having conversations with Customers.

Bob Bridge & I talked with Steve Mogensen & Brian Kopp. Both are very nice people, good backgrounds & appeared Competent. Product seems solid but Brian did indicate that Gen2 may not been delivered until 2021 or 2022. Brian seemed to believe it was a very critical Enhancement.

Financial Due Diligence: Scorecard of 2-Potentially Problematic. Brian seems competent. He would do well with a Senior Financial Person provided him Direction. He will be going through a learning process. Hopefully, it will not be detrimental to SpeechVive.

Executive Summary-Rank Financials: a 3 based upon possible improvement in CFO who has only been on board for 3 months.

Team & Operating Ability: The Team has not been able to stay on Plan-Major Negative to have to cut all salaries in 2019. Appears that Team was not able to raise Funds in 2018 & 2019 to adequately fund the Company.

Product & Technology; Need to study impact on SpeechVive if Gen2 Enhancements are delayed.

Competition: Competitive Advantage seems strong.

Deal Terms: Cap of $8 Million seems too High. Could be deal breaker.

Financial Model: Assumptions regarding Rate of Growth seem too aggressive. Need to develop a Contingency Plan with much much slower Growth and establish a Breakeven plan.

Price of Product seems much lower as compared to Value to Customers & Competition.

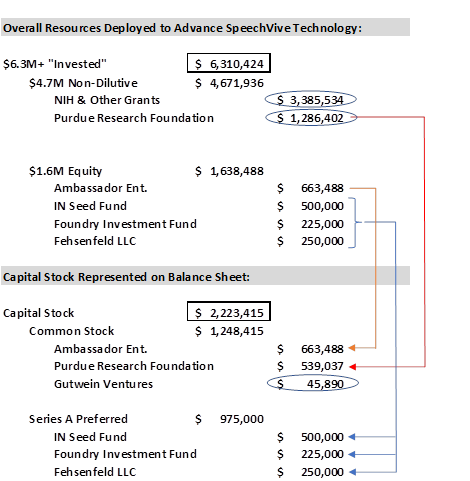
**Further Notes from company on amount of money previously raised:**

As a follow-up to our call, please see the below detail reconciliation between the “$6.3M+ Invested” slide from the Pitch Deck and the $2.2M of Capital Stock highlighted in the Balance Sheet.

The fundamental difference is that we desired to provide a comprehensive view of total resources that have been dedicated to advancing the SpeechVive technology in our Pitch Deck. For accounting purposes, however, the Grant funding and a portion of the Purdue “contributions” are not reflected in the Balance sheet. The Balance sheet accurately reflects Equity holding/obligations, but likely under-represents “assets” that are a product of the Grant and other non-dilutive funding. As you likely know, R&D is almost always expensed and not ascribed to assets.

Considerations:

* All of the “Equity” highlighted in the Pitch Deck is reflected in Capital Stock, and a portion of the “Non-Dilutive”
  + $539k of the total Purdue Research Foundation “investments” were structured as Convertible Debt initially, then converted to Common Stock. This portion was the requested consideration for all prior services and resourcing provided by the university for the SpeechVive Technology. It was a negotiated outcome in total, not necessarily associated with specific resource elements.
  + Purdue-related funding associated with various research and product development aspects
    - ($483k) Pilot device (hardware and app) development
    - ($603k) Commercial device (hardware and app) development
    - ($200k) Business planning and strategy development
* NIH & Other Grants not represented on Balance Sheet
  + No associated Equity instrument, or outstanding obligation
  + Funds utilized for various research and development
    - ($2,096k) Study/Trials – Use of External Cueing to Treat Hypophonia in Parkinson’s Disease
    - ($1,252k) Development of Telehealth platform – IT platform utilized to calibrate devices to individual patient needs
    - ($38k) misc. clinical data gathering and research
* Common Stock associated with Gutwein Ventures ($46k) was issued to recognize services-in-kind, and is not represented as an “investment” in the Pitch Deck slide



# Appendix – additional notes that support the one-page summaries above

*Social Impact*

*Number of total patients receiving a SpeechVive device*

342

 *Number of patients receiving a SpeechVive through the VA*

276

 *Number of patients receiving a SpeechVive through Medicare*

4 (just started filing claims in 2019)

 *Number of patients receiving a SpeechVive through Commercial insurance providers*

3

 *Number of total patient/caregiver events attended by SpeechVive (Victory Summit, support groups, etc.)*

8 (in 2019. More planned with additional resources in 2020)

# Questions that need to be answered by the company before the memo can be completed

Attachment - Company Provided Information

Company Pitch Deck

Company Application form

Company Supplemental Information form

Other documents