

## **AASM Change Agents Executive Summary**

Just as it takes a village to raise a child, we think it takes a village to help treat a chronic medical condition like obstructive sleep apnea (OSA). The current processes of diagnosis, treatment, and long-term adherence to therapy for OSA are often confusing and fragmented. Many at-risk patients may not only be challenged to find a qualified sleep provider, but they may also get lost along the way. We believe the process needs to be re-defined in a way that is evidence-based, patient-centered, and adaptable to the needs of the people it is meant to serve. We believe that by building a technological platform to better align resources to patients, clinicians, and others, the care of patients with OSA will be improved. We therefore introduce MySleepVillage (mySV) as the proposed solution to revolutionize the care of patients with OSA and other sleep disorders.

mySV is a publicly accessible mobile health website with app features-- a virtual patient navigator -- that provides patient education, access to sleep clinicians, and integrates others in the sleep and health industry. There will be additional subscription services that allow for enhanced functionality, either at the patient level, the clinicians/office level, or at the level of other key stakeholders.

By centralizing these applications, mySV would serve as a vital clinical resource, to improve clinical outcomes while enhancing the overall experience. It would also allow for personalized and precision medicine to be available to every user while simultaneously providing an avenue for sleep-based research and innovation. As such, the successful app would provide the infrastructure for successive applications that serve patients with other sleep-related issues.

We estimate mySV to cost just \$899,242 for full operations and personnel, with a 5-year margin projected at \$7,631,298. We believe the value to society to be even far greater than the positive ROI.

SWOT analysis of the current situation revealed the following highlights. The checkmarks represent weakness concerns and opportunities that are addressed by our proposal:

### **Strengths:**

- Patient-engaged physicians and experienced technologists
- Recent improvements in patient access to care (eg. HSATs and Telemedicine)
- Many options to address the vast difference of patient need and conditions
- General sleep interest and support is on the rise
- Advancements in device technology reducing procedural costs and repeat studies
- Growth in sleep research and patient education.

### **Weaknesses:**

- ✓ Existing workforce shortages in sleep physicians and sleep technologists
- ✓ Difficult for patients to navigate existing process of screening, consultation, diagnosis, therapy, and follow-up
- ✓ Disparities for underserved populations
- ✓ Lower than desirable adherence to therapeutic care
- ✓ Low and inconsistent reimbursement. Insurance weighing cost vs. cost savings when making reimbursement changes
- ✓ Research usually not personalized, nor sleep disorders viewed as a chronic disease.

### **Opportunities:**

- ✓ Streamline physician process to allow more visits and patient interactions. Create a holistic vs. episodic approach to comorbid conditions
- ✓ Expand personalized medicine and more options allowing alternatives for diagnosis and therapy
- ✓ Make a fun and trusted navigation tool to improve access, choices, address cost, and enhance experience. The approach should be personal, scientific, and simple.
- ✓ Better sleep has an explosive potential market with many potential consumers
- ✓ Better demonstrate significant reduction in overall healthcare and costs when patients adhere to care.
- ✓ Establish a registry of sleep data to support research and better outcomes.

### **Threats:**

- Technology disruptors discounting the importance of the sleep physician and technologist
- Further reimbursement reductions by CMS and insurance carriers
- Amazon, Walmart and other retail outlets issuing diagnostics and therapy without prescriptions
- Patient factors for adherence – RLS, PTSD, insomnia
- Low patient diagnostic engagement and therapy adherence. CMS possibly discontinuing PAP reimbursements
- Reduction of research and education funding

The current process for being screened, diagnosed and treated for obstructive sleep apnea is complicated and confusing for most individuals. Which person or clinician do I see first? Do I need to tell my primary care doctor? Should I go straight to a specialist? Can I get treated online? Why are they sending me to a hospital when my friend just had a study at home? Why would I go through all this and end up on CPAP? Why can't I just get a CPAP today? Why does this process take so long? Why are there so many choices and to whom do I go to for advice?

One common complaint from patients is the lack of communication and transparency along the process. mySV serves to support the patient as they move through the process from screening, to diagnosis, to treatment and ongoing adherence. Once a patient has decided they would like to pursue a clinical evaluation, they are able to find a Sleep Clinician in their area. They are able to schedule either an in-person clinic visit, or a telemedicine visit with a licensed sleep medicine provider. Messaging about appointment date, time, and reminder messaging are automatically generated to keep the patient informed. Once the clinic visit occurs and an order for testing has been placed, the mySV messaging technology will update the status of the patient. Patients can visually see their chosen path and their progress. Once insurance has approved the testing, a message will inform the patient that they are able to now schedule their sleep test. mySV provides messaging to the patient along each step, a piece which is currently not standard of care. This allows the patient to remain in control of the process while also being updated in real time. If there are questions that arise, an intelligent chat box fields the first layer of questions, most of which will adequately answer the patient's queries. This serves to offload work from support staff in sleep clinics and allows them to function more efficiently, therefore providing greater satisfaction with the process for both patients and clinical staff.

Once a patient undergoes a sleep test, results are provided to the patient as soon as the interpretation has been approved. There is a sleep coach available to discuss these results either over the phone or via telemedicine where their sleep test recommendations are reviewed, and treatment options presented. Once the patient decides upon a treatment option and has chosen a home medical equipment provider (HME), a script is generated for the sleep provider to sign. This also shifts workload from clinical staff to mySV sleep coaches.

Adherence is monitored via an opt-in protocol – the patient remains in control. If they wish for ongoing monitoring to be performed, they sign a consent form outlining the processes and the possibility of future billing via the Remote Patient Monitoring (RPM) codes. If a patient chooses this pathway, their data will be uploaded to a secure cloud where the clinical staff is able to review this patient-generated health data from their patients' CPAP devices. The cloud-based platform is secure and HIPAA-compliant. Each time a clinician views the data, there is a time-date stamp. Once the clinician has spent the required amount of cumulative time and reviewed the appropriate amount of data, a secure email is generated outlining every minute spent reviewing the data and suggests an appropriate RPM code. If a patient's data review falls short of these set parameters, no email is generated. This serves to eliminate the burden of documentation from the clinician while also capturing workload that passes the threshold to qualify for reimbursement.

The mySV app creates a community for the patient via the community center, in addition to providing direct links to educational materials via the library, financial information via the bank, and even gamification by allowing the upload and dashboard display of patient-generated health data via consumer sleep technology. This allows members who so choose to then compare their metrics to their peers and encourages competition to develop

healthy sleep habits. With patient permission, data throughout the process can be used as a registry source for improving best practice and developing processes that improve the patient experience and outcome. There is an area devoted to pediatrics with specific educational materials and engaging videos to support the pediatric population.

mySV strives to re-imagine the patient experience and is based on years of clinical experience in various health care settings. The structure lends itself to future growth to include all sleep disorders and other non-sleep disorders. By extrapolating from AASM data, if 10,000 users go through the mySV process, we anticipate this could yield \$42 million dollars in health care savings.

## **SITUATION ANALYSIS:**

Currently, the OSA pathway is fragmented and inconsistent. There are many opportunities for patients to be lost as they try to navigate through the health care system. Improving access, streamlining the process, and ensuring the patient is provided with proper education and coaching will help far more individuals complete the journey<sup>1</sup>. A personalized journey that addresses differences and complexities will ensure greater patient engagement throughout and provide the desired health outcome results<sup>2</sup>.

OSA diagnosis and management centers around the patient presenting to a clinician for a history and examination, followed by diagnostic testing to see if treatment and which treatment is optimal. For many patients that are diagnosed with OSA, that treatment leads to a prescription of Continuous Positive Airway Pressure (CPAP), which is then provided by a local or national Home Medical Equipment (HME) company. Typically, the costs of CPAP are then reimbursed by a health insurance company or third-party payor. The process has served many patients successfully, with many studies demonstrating improvements in health outcomes, and the public is more commonly aware of the potential benefits. However, numerous studies have demonstrated this process to miss over 80% of patients at risk<sup>3</sup>, and many that continue through this process end up not being treated effectively. Access is a large concern for many, especially where there are shortages of sleep professionals or other disparities in healthcare. Moreover, reimbursement is centered around office visits, diagnostic testing, and treatment options, all of which are decreasing in potential reimbursement. Despite the increasing public interest in diagnosing and treating OSA, the financial model is leaving sleep practices at financial risk.

We have outlined the various strengths, weaknesses, opportunities, and threats across 6 domains – the sleep clinical workforce, the patient experience, the process, market dynamics, reimbursement, and research/education. Please refer to **Appendix A**.

**Sleep Clinical Workforce:** For the most part, sleep clinicians are talented, well educated, experienced and engaged physicians, advanced practice providers, and sleep technologists. Unfortunately, there are not enough sleep physicians. There are also declining sleep technologist school enrollments. With 80% of OSA remaining undiagnosed,<sup>4</sup> this is a

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<sup>1</sup> de Batlle J, Massip M, Vargiu E, Nadal N, Fuentes A, Ortega Bravo M, Miralles F, Barbé F, Torres G; CONNECARE-Lleida Group. Implementing Mobile Health-Enabled Integrated Care for Complex Chronic Patients: Intervention Effectiveness and Cost-Effectiveness Study. JMIR Mhealth Uhealth. 2021 Jan 14;9(1):e22135.

<sup>2</sup> Billings ME, Cohen RT, Baldwin CM, Johnson DA, Palen BN, Parthasarathy S, Patel SR, Russell M, Tapia IE, Williamson AA, Sharma S. Disparities in Sleep Health and Potential Intervention Models: A Focused Review. Chest. 2021 Mar;159(3):1232-1240

<sup>3</sup> Frost and Sullivan. Hidden Health Crisis Costing America Billions. American Academy of Sleep Medicine. 2016.

<sup>4</sup> Frost and Sullivan. Hidden Health Crisis Costing America Billions. American Academy of Sleep Medicine. 2016.

significant weakness for the sleep workforce. As a result, sleep clinic appointments may be delayed by weeks or months. These excessive wait times that can discourage individuals from taking action or completing the process. This need for a larger workforce has created several opportunities. By improving clinic efficiencies (by creating a team of clinical experts and a robust set of educational resources), we aim to increase clinic revenue through increased patient volumes, being respectful of workforce shortages and extending their capacity by offloading some of the workload to a sleep team. Telemedicine has increased access to patient care and advancements in technology, including both disposable and non-disposable HSATs, have allowed sleep testing to be conducted safely in the home. This continued advancement in technology, however, is now a threat as consumer-facing sleep technology is now entering quickly into the diagnostic realm without clear patient safeguards. This significantly threatens clinician reimbursement and may eliminate what is currently a strong revenue stream for most practices.

**Patient Experience:** Recent improvements in technology have allowed for a significant portion of the population to be tested at home. Therapeutic advancements have also increased the potential effectiveness and personalized individual options for patient choice. New devices for treating OSA and improved PAP interfaces provide the clinical team excellent options to meet individual needs and differences.

Telemedicine has gained popularity over the past year and can be an excellent solution for sleep consultations providing both convenience and access for many patients. From software to enhance technologist scoring to apps that identify an ideal PAP mask, supportive technology abounds. There are robust educational materials produced for individuals to learn more about obstructive sleep apnea and other comorbid sleep conditions. All of these have improved the patient experience. Despite these advancements, it is still difficult for patients to navigate the process. There are too many places where the patient journey is derailed as there isn't a robust process to shepherd patients through the current model. This is highlighted by sleep health disparities where only 5% of African American men have a diagnosis of OSA despite being in a higher risk group than Caucasians<sup>5</sup>.

The advancements in OSA treatment options allow for more personalized care. Emerging data about various OSA phenotypes also allow clinicians to make educated decisions on which patients need to be treated and which treatment option is most appropriate for that patient, incorporating their testing results with patient preference, anthropomorphic features, and personomics. The single greatest obstacle in the patient experience centers around insurance and payment for testing and treatment. This continues to be a significant threat to the patient experience.

**Process:** We now possess more options to address patient needs. Health systems are striving to improve communication with their patients, and the recent open notes

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<sup>5</sup> Johnson DA, Guo N, Rueschman M, Wang R, Wilson JG, Redline S. Prevalence and correlates of obstructive sleep apnea among African Americans: the Jackson Heart Sleep Study. *Sleep*. 2018;41(10)

legislation<sup>6</sup> has resulted in more transparency. Patient portals allow for asynchronous communication with health care providers at the patient's convenience. These are all significant strengths however they are not enough to overcome the weaknesses in the patient process. This is still a long, fragmented process from identification of at-risk patients through evaluation, diagnosis, and treatment. Patients often receive bills from multiple sources that are often not connected– the clinic, the sleep lab, the HME company and this adds to confusion. Insurance coverage is opaque and often leads to delays in care. If patients are deemed to be non-adherent to care, the insurance company dictates that devices need to be returned rather than providing interventions or support to improve adherence. This creates an opportunity to create a patient-centered navigation tool to improve access, choice, address costs, and enhance the patient experience. Before this can even be effectively implemented, it faces significant threats from consumer giants such as Amazon and Walmart in addition to other retail outlets providing sleep testing and treatment without a prescription.

**Market Dynamics:** By all web-based and social-media metrics, interest in sleep and sleep disorders continues to climb<sup>7</sup>. The public's acceptance of the importance of sleep has changed and more consumers are looking for ways to improve their sleep. Unfortunately, there continues to be sub-optimal adherence to treatment options. These two forces create an opportunity for consumers to explore other ways to improve their sleep, such as via luxury sleep items (weighted blankets, eye masks) and education about sleep and sleep beliefs and misperceptions (brief behavioral interventions via app or telemedicine). This opportunity is also a threat as patients may not seek evaluation of an underlying sleep disorder opting, instead, to purchase a new mattress.

**Reimbursement:** Advancements in technology have allowed testing to become more efficient, often performed in the home in one night compared to two in-lab studies previously. This is a strength as it allows the patient to be diagnosed and treated more quickly, however, lowering reimbursement and insurance resistance can negate the hope for financial expediency. By focusing on population health rather than the cost of sleep testing, payors could realize significant cost savings by diagnosing and effectively treating sleep disorders. This recently was a contentious topic as CMS has focused on reduction of cardiovascular risk by using PAP therapy and have not found enough evidence to support the use of CPAP<sup>8</sup>. There is a significant threat posed by this line of reasoning both for HMEs and clinicians. This will also inadvertently create mixed messaging for patients regarding the importance of treating their sleep disorder and will likely cause undue financial burdens for our patients.

**Research and Education:** Patients now have access to robust sleep education online. Reputable organizations, such as the Mayo clinic and the AASM contribute to this large

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<sup>6</sup> <https://www.opennotes.org/onc-federal-rule/> Accessed 5.20.2021

<sup>7</sup> Zitting K-M, Lammers-van der Holst HM, Yuan RK, Wang W, Quan SF, Duffy JF. Google Trends reveals increases in internet searches for insomnia during the coronavirus disease 2019 (COVID-19) global pandemic. *J Clin Sleep Med.* 2021;17(2):177–184.

<sup>8</sup> <https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/ta/drafts-for-review/sleep-apnea-draftreport.pdf>

body of work and patients are now more informed. Despite this, there is still a paucity of outcomes-based data regarding the benefits of treating OSA. This provides yet another opportunity to utilize data collected within the app/website to create a sleep registry. This may allow future insights into comorbid conditions and explore if there is a benefit to earlier diagnosis and treatment to prevent cardiovascular disease at an earlier stage – perhaps these changes have already occurred by the time the patient is diagnosed with OSA and may partly explain the lack of observable effect in many studies. Unsurprisingly, reduction of research and educational funding poses a threat to future work in this domain, as well as threatening current reimbursement paradigms.

Two tremendous opportunities that could result from this navigation tool includes:

1. **A significant reduction in overall healthcare costs<sup>9</sup>** for the patients who complete the screening, diagnosis, and treatment process and are adherent to care have a much lower cost of overall healthcare expenses. This reduction in costs can be in excess of 30% vs. patients who remain untreated. \*Sleep disorders are associated with significantly higher rates of healthcare utilization and expenditures. The overall incremental healthcare costs of sleep disorders in the US represents approximately \$94.9 billion.
2. **A robust population health data base** the usage of the tool could provide a tremendous amount of technical, physiologic and demographic data that could be used for research and, in turn, best practice to personalize care for various individuals who suffer from sleep apnea. Knowing what has been proven to be effective for patient cohorts (age, weight, gender, biometrics and similar symptoms) and how their journey compares to others could benefit the patient directly as well as many others over time.

There is an opportunity to make a fun and trusted navigation tool to improve access, increase choices, and enhance the experience that could be personal, easy and meet scientific guidelines and standards. This navigation tool could have a massive potential market. It could begin to address the 80% undiagnosed OSA population, speed up the process, improve transparency and communication, decrease confusion and touch points and make the journey very worthwhile for both patient and health care professional.

## **SOLUTION FRAMEWORK<sup>10</sup>**

### **mySleepVillage (mySV)**

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<sup>9</sup> Incremental health care utilization and expenditures for sleep disorders in the United States Phillip Huyett, MD1; Neil Bhattacharyya, MD, MA, FACS2 <https://jcsn.aasm.org/doi/10.5664/jcsn.9392> Accessed 5.20.2021

<sup>10</sup> [themanifest.com/app-development/what-is-mobile-app-marketing](http://themanifest.com/app-development/what-is-mobile-app-marketing)



## Costs / Delivery Model / Stakeholders (Buy-in)<sup>11</sup>

### Investors | Ownership | Delivery Model

The AASM has a unique opportunity through mySV to bring to the market a new company that connects patients to resources and clinical services to treat sleep apnea via an App and website. mySV will be a subsidiary of the American Academy of Sleep Medicine but may also include outside investors with similar goals in increasing awareness, engagement, diagnosis, and treatment of Sleep Apnea as a joint venture. Potential Joint Venture Partners include: ResMed, Philips, SleepScore Labs, Jazz Pharmaceuticals, 3B, Fisher & Paykel, Apple, and Google.

### Key Stakeholders

- Sleep Apnea Patients – Diagnosed / Undiagnosed
- American Academy of Sleep Medicine
- Sleep Medicine Physicians
- PAP Manufacturers – ResMed, Philips, F&P
- HME and Diagnostic Sleep Providers
- Health Technology Companies
- Third Party Administrators / CMS / Commercial Payors

### Capital Investment

Initial capital investment will be \$899,242.00. This will fund initial CAPEX, Software Development, Employee Costs and Working Capital. The table below outlines how the initial investment funds will be allocated:

Uses of Funds		
CAPEX	USD	200,000
Development Costs	USD	350,000
Paid Ads	USD	75,000
Operations	USD	37,987
Reserve	USD	236,254
Debt Service	USD	0
<b>Total</b>	<b>USD</b>	<b>899,242</b>

### Revenue

Revenue is generated by monthly and annual subscribers to the mySV app and in-app advertisements.

**Monthly subscription cost for app - \$9.99** (80% of subscribers)

**Annual subscription cost for app - \$79.99** (20% of subscribers)

**Ad Revenue (Ads displayed per hour) - 4 x.\$40 = \$1.60 per hour per user (per click)**

**Ad Revenue (Ads displayed per hour) - 4 x.\$40 = \$1.60 per hour per user (impressions)**

### Budget (Projections)

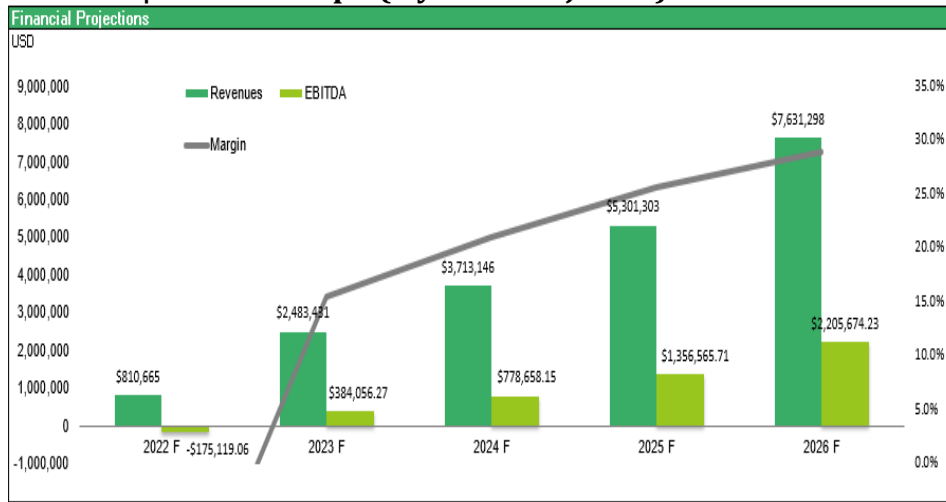
2022	<b>*Revenue - \$810,665</b>	EBITDA - (\$175,119)
2023	<b>*Revenue - \$2,483,431</b>	EBITDA - \$384,056

<sup>11</sup> <https://www.kleinerperkins.com/perspectives/internet-trends-report-2018/>

2024	<b>*Revenue - \$3,713,146</b>	EBITDA - \$770,650
2025	<b>*Revenue - \$5,301,303</b>	EBITDA - \$1,356,566
2026	<b>*Revenue - \$7,631,298</b>	EBITDA - \$2,205,674

\*NOTE – Revenue does not currently include annual partner dues related to data access or integrations to app. These revenue opportunities will be determined based on scope and scale of request.

### Revenue | EBITDA Graph (5 year - Projected)



### Operating Expenses (5 year - Projected)

Costs	Start	2022 F	2023 F	2024 F	2025 F	2026 F
<b>CAPEX</b>						
CAPEX	USD	100,000	50,000	50,000	50,000	50,000
Software Development (Activated)	USD	200,000	75,000	75,000	75,000	100,000
<b>COGS</b>						
Commissions App Stores	USD	(224,809)	(573,089)	(833,109)	(1,173,374)	(1,676,581)
Direct costs I /Active User	USD	0.48	0.30	0.20	0.10	0.05
Direct costs II /month	USD	4,000	6,000	10,000	10,000	10,000
Direct costs III % of Sales	% of Sales	25.0%	25.0%	25.0%	25.0%	25.0%
<b>FTEs</b>						
C-Level Management	#	3.0	4.0	5.0	5.0	5.0
Middle Management	#	1.0	1.0	1.0	1.0	1.0
Staff	#	1.0	2.0	3.0	3.0	3.0
<b>OPEX</b>						
Employee expenses	USD	288,000	336,000	384,000	384,000	384,000
Travel expenses	USD	12,000	12,000	12,000	12,000	12,000
Marketing - Paid Ads	USD	0	0	0	0	0
Marketing - General	USD	30,000	50,000	50,000	50,000	50,000
Software Development (Expense)	USD	0	0	0	0	0
Hosting	USD	5,000	5,000	10,000	15,000	15,000
External services	USD	5,000	5,000	5,000	5,000	5,000
Office lease	USD	7,500	7,500	7,500	7,500	7,500
Property/community tax	USD	2,400	2,400	2,400	2,400	2,400
Insurance	USD	1,200	1,200	1,200	1,200	100
Other - Variable Costs	% of Sales	15.0%	15.0%	15.0%	15.0%	15.0%
Other - Fixed Costs	USD	121,600	372,515	556,972	795,195	1,144,695
Contingencies	USD	500	500	500	500	500
<b>Total</b>	<b>USD</b>	<b>474,200</b>	<b>793,115</b>	<b>1,030,572</b>	<b>1,273,795</b>	<b>1,622,195</b>
% of Sales	%	58.5%	31.9%	27.8%	24.0%	21.3%
<b>EBITDA</b>	<b>USD</b>	<b>(175,119)</b>	<b>384,056</b>	<b>778,658</b>	<b>1,356,566</b>	<b>2,205,674</b>
Margin	%	-21.6%	15.3%	21.0%	25.6%	28.9%
Check		-30,000	-45,000	-67,500	-101,250	-151,875

## App Downloads and Active Users (Projections) – Assumes 50% YOY growth and 5% Churn rate.

App Downloads and Active Users		2022 F	2023 F	2024 F	2025 F	2026 F
<b>Organic App Downloads</b>						
Organic App Downloads	#	75,000	112,500	168,750	253,125	379,688
Growth Organic App Downloads	%	NA	50.0%	50.0%	50.0%	50.0%
Growth Rate adj. For Scaling Factor	%	NA	50.0%	50.0%	50.0%	50.0%
<b>Paid App Downloads (Ads)</b>						
Marketing Budget - Paid App Downloads	USD	30,000	45,000	67,500	101,250	151,875
Growth	%	NA	50.0%	50.0%	50.0%	50.0%
Cost per Click	USD/Click	0.20	0.21	0.22	0.23	0.24
Download Conversion	%	5.0%	4.5%	4.0%	4.0%	4.0%
Customer Acquisition Costs (CAC)	USD/Download	4.00	4.67	5.50	5.75	6.00
<b>Total App Downloads</b>						
Organic App Downloads	#	75,000	112,500	168,750	253,125	379,688
Paid Downloads	#	7,500	9,643	12,273	17,609	25,313
<b>Total App Downloads</b>	<b>#</b>	<b>82,500</b>	<b>122,143</b>	<b>181,023</b>	<b>270,734</b>	<b>405,000</b>
<b>KPIs</b>						
New App Downloads	#	82,500	122,143	181,023	270,734	405,000
App Installs	#	73,715	156,798	265,407	418,391	640,722
Active Users	#	36,857	78,399	132,704	209,196	320,361
Subscribers	#	6,085	9,807	13,873	19,610	28,230
Per User ARPU per month	USD	1.83	2.64	2.33	2.11	1.99
Per Subscriber ARPU/month	USD	23.99	23.99	23.99	23.99	23.99
Total MRR	USD	763,189	2,289,964	3,357,740	4,725,088	6,738,478
Subscription MRR	USD	145,982	235,265	332,808	470,443	677,230

## Infrastructure Requirements Administration | Governance

Administrative oversight and leadership of mySV will be comprised of designated members the Board of the American Academy of Sleep Medicine (AASM) and any investor company designees.

Clinical policy oversight will be performed by committee members selected by the AASM.

## Human Capital | mySV staff

mySV will utilize the AASM's current human resources services to recruit, hire and maintain the employment of staff for the company. Please refer to **Appendix B** for detailed job descriptions, qualifications, and employee responsibilities.

Initial employment opportunities will include:

1. Executive Director – \$132,000 (estimated compensation)
2. Senior Software Manager – \$132,000 (estimated compensation)
3. Technical Support Specialist – \$48,000 (estimated compensation)

## Software Integrations

mySV will be integrated with multiple applications including:

1. SleepTM (AASM) – Sleep Medicine Consults
2. Sleep CDR (AASM) – Sleep Clinical Data Registry
3. Care Orchestrator (Philips) Airview (ResMed)
4. Sleep Trackers (Various)

## 5. eCommerce

Typical integrations include Application Programming Interface (API) integrations between programs. This is a software-to-software interface that defines the contract for applications to talk to each other over a network without any user interaction. It is a code that allows software programs to communicate with each other.

### **Outsourced Services | Technology**

mySV will outsource a number of services including:

1. *Web Hosting* - A web hosting service (often shortened to web host) is a type of [Internet hosting service](#) that allows individuals and organizations to make their [website](#) accessible via the [World Wide Web](#). Web hosts are companies that provide space on a [server](#) owned or leased for use by clients, as well as providing [Internet](#) connectivity, typically in a [data center](#).
2. *Software Systems Development* - Systems development is the process of defining, designing, testing and implementing a new software application or program.
3. *App/Web Marketing* - Mobile app marketing is about creating marketing campaigns that communicate with your users at every stage of their life cycle: from when they first download your app, to when they become a regular user and brand advocate who makes many in-app purchases.

### **Communications Plan (Marketing)**

Communications and Marketing will initially be performed by the same resources currently being utilized by the AASM.

The goal for the mySV app is to get users to install it on their personal devices and then to drive continued engagement. The AASM will promote the mySV app on its website and in communication blasts to its members. Also, app partners will be tasked with assisting in the promotion of the app through their own resources.

While traditional website marketing relies on search engine optimization (SEO), app store optimization (ASO) is the equivalent [strategy needed to promote the app](#). Optimizing the app's listing with ASO will ensure it appears at the top of the search results in the app store — which is necessary, since consumers have millions of apps to choose from.

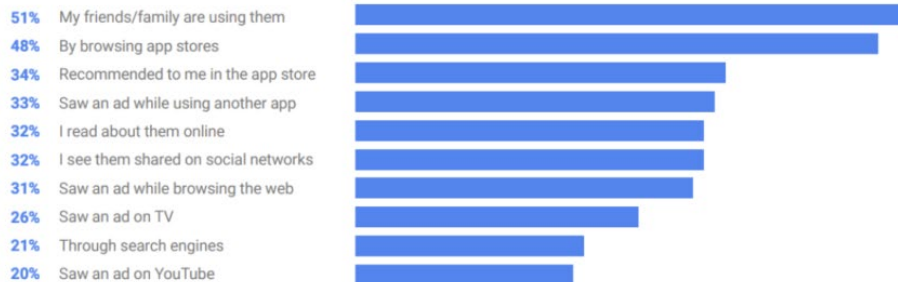
Ultimately, [the aim of ASO](#) is to boost brand exposure and audience engagement, as well as to get positive app reviews and ratings (these help further boost app sales and downloads). Fortunately, several SEO methods can be successfully used for ASO. This includes ASO keyword research, click through rate (CTR) optimization, indexing the app in Google SERPs, optimizing app title, name, and URL, and generating and managing app ratings and reviews.

Initial budget for marketing is \$30,000 and will increase year-over-year (YOY) to \$50,000.

What makes users select an app? Things to consider when marketing the app.

## To discover new apps, people turn to those they trust: friends and family

### Top methods of app discovery



Base: 999  
Q32. How do you typically find out about new smartphone apps?  
Q33. And have you found out about an app in any of these ways?

think with Google

mySV is uniquely positioned in the market as there are currently no sleep health consumer clinical apps in the top ten most downloaded sleep apps.

### Current Top 10 Sleep Apps<sup>12</sup>

1. Headspace
2. Noisli
3. Pzizz
4. Slumber
5. Calm
6. Sleep Cycle
7. 10% Happier
8. Reflectly
9. Sleepiest
10. Moshi

### **ANTICIPATED IMPACT**

Any successful intervention enhancing the diagnosis and management of patients with OSA will significantly impact each component of medicine's triple aim, from population health to individuals' care experience to per capita cost control. mySV, a novel mobile health (mHealth) application will do just that. There is little doubt that a large *potential* patient population exists that we are not reaching. A 2016 report commissioned by the AASM showed that 24.9 million American have OSA, but only 5.9 million (20%) American are diagnosed. Having 80% of Americans with OSA undiagnosed (and therefore untreated) places tremendous burden on the health care system through exacerbated medical comorbidities and reduced workplace productivity. Taken together, the report estimates that undiagnosed OSA cost the United States \$146.9 billion in 2015. When broken down per capita, diagnosing and treating OSA cost \$2,105 per person whereas undiagnosed OSA cost

<sup>12</sup> <https://www.goodhousekeeping.com/health/wellness/g26963663/best-sleep-apps/>

\$6,366 per person.<sup>13</sup> mySV directly targets these opportunities for improvement in population health while providing app users with a patient-friendly interface through which to access the sleep medicine system. It will do this through its inherent flexibility, accessibility, and technological innovation (artificial intelligence [AI]).

We believe the mySV app may help address some key disparities in sleep health care that impact socio-economically disadvantaged groups disproportionately. Recent work in the Latinx population showed that, while 14% of the study cohort met AHI criteria for moderate or severe OSA, only 1% of the group had been previously diagnosed.<sup>14</sup> Similarly, an African American cohort showed 24% positivity for moderate or severe OSA, but only 5% of those individuals were already diagnosed.<sup>15</sup> Those disparities extend beyond just disease identification. There is evidence that African-Americans are less likely to follow-up with sleep providers and have lower adherence to OSA treatment.<sup>16</sup> Mistrust in the medical system and perceptions of implicit biases may drive some of these observations.<sup>17</sup> One recent review of sleep medicine disparities states, “The high-prevalence and yet underrecognized aspects of sleep apnea create a need for innovative models of care that embrace new technologies and leverage the realignment of traditional provider roles in an attempt to mitigate sleep health disparities...”<sup>18</sup> Our app is a response to that call to action by leveraging technology to better reach and support these groups.

How can disadvantaged groups find and benefit from mySV? Access flexibility is key. mySV “Village Tourist” access will be available *for free* as a:

- smartphone app (for those individuals with smartphones)
- website (for anyone with internet access)
- downloadable off-line tracking tool (if continuous internet access is unreliable).

Access flexibility is a concept not limited to the app itself. mySV will be accessible through different electronic mediums, but how do groups learn that it exists? mySV will be made available through workplace human resource departments, primary care clinics, community centers, and general public health initiatives. For individuals already using fitness trackers or fitness equipment, the app will be offered as an add-on that integrates fitness and sleep data to optimize personalized guidance (technological innovation) as part

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<sup>13</sup> Frost and Sullivan. Hidden Health Crisis Costing America Billions. American Academy of Sleep Medicine. 2016.

<sup>14</sup> Redline S, Sotres-Alvarez D, Loreda J, et al. Sleep-disordered breathing in Hispanic/Latino individuals of diverse backgrounds: the Hispanic Community Health Study/Study of Latinos. *Am J Respir Crit Care Med*. 2014;189(3):335-344.

<sup>15</sup> Johnson DA, Guo N, Rueschman M, Wang R, Wilson JG, Redline S. Prevalence and correlates of obstructive sleep apnea among African Americans: the Jackson Heart Sleep Study. *Sleep*. 2018;41(10)

<sup>16</sup> Pandey A, Mereddy S, Combs D, et al. Socioeconomic inequities in adherence to positive airway pressure therapy in population-level analysis. *J Clin Med*. 2020;9(2):442.

<sup>17</sup> FitzGerald C, Hurst S. Implicit bias in healthcare professionals: a systematic review. *BMC Med Ethics*. 2017;18(1):19.

<sup>18</sup> Billings ME, Cohen RT, Baldwin CM, Johnson DA, Palen BN, Parthasarathy S, Patel SR, Russell M, Tapia IE, Williamson AA, Sharma S. Disparities in Sleep Health and Potential Intervention Models: A Focused Review. *Chest*. 2021 Mar;159(3):1232-1240

of its “Village Member” and “Village Premium” access plans. Therefore, mySV users will be able to learn about, access, and use the app regardless of group or socioeconomic status.

The mySV app was also developed with the pediatric population in mind. Unfortunately, OSA is likely underrecognized and undertreated in children, with between 1.2% and 5.7% of children meeting criteria for OSA.<sup>19</sup> Since there are approximately 74 million children (individuals under age 18) in America<sup>20</sup>, up to 4.2 million American children may have the disorder. Furthermore, OSA appears to preferentially affect African Americans compared to non-Latinx white children with worsened severity at the time of diagnosis.<sup>21</sup> African American children also seem to show less improvement with OSA treatment than white children.<sup>22</sup> Beyond race factors, children living in less socioeconomically-advantaged neighborhoods also appear to have higher risk of having OSA.<sup>23</sup> Reasons for these disparities are still being explored, but the evidence is clear that there are large numbers of children in America with OSA who may not be effectively screened or treated for it. mySV provides a user-friendly interface, free of charge in its “Village Tourist” form, that parents can share with their children as they travel together on a journey toward sleep health. For instance, children and their parents can visit the Village’s “fairground” where gamification engages them all as they learn more about OSA. But how feasible is an mHealth platform for children and adolescents? A recent qualitative assessment of low-income and minority adolescents’ attitudes toward a smartphone app found them receptive to this method of sleep education and tracking. The authors found good adherence, engagement, and perception of health benefits with the use of 2 commercially available non-sleep related apps.<sup>24</sup> mySV is expected to show similar results.

To summarize, there is a large potential-patient pool of adults and children who must be identified as needing OSA testing, treatment, and ongoing management. The market is there, and mySV will have a significant impact on improving population health and experience of care (2 main elements of medicine’s triple aim). But are there not other sleep-related apps already on the market? What makes mySV any different? Indeed, a recent sleep-related smartphone app review showed that over 2,400 sleep-related apps

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<sup>19</sup> Marcus CL, Brooks LJ, Draper KA, Gozal D, Halbower AC, Jones J, Schechter MS, Ward SD, Sheldon SH, Shiffman RN, Lehmann C, Spruyt K; American Academy of Pediatrics. Diagnosis and management of childhood obstructive sleep apnea syndrome. *Pediatrics*. 2012 Sep;130(3):e714-55.

<sup>20</sup> The Changing Child Population of the United States. [www.aecf.org](http://www.aecf.org). The Annie E. Casey Foundation. Accessed May 6, 2021.

<sup>21</sup> Rosen CL, Larkin EK, Kirchner HL, et al. Prevalence and risk factors for sleep-disordered breathing in 8- to 11-year-old children: association with race and prematurity. *J Pediatr*. 2003;142(4):383-389.

<sup>22</sup> Marcus CL, Moore RH, Rosen CL, Giordani B, Garetz SL, Taylor HG, Mitchell RB, Amin R, Katz ES, Arens R, Paruthi S, Muzumdar H, Gozal D, Thomas NH, Ware J, Beebe D, Snyder K, Elden L, Sprecher RC, Willging P, Jones D, Bent JP, Hoban T, Chervin RD, Ellenberg SS, Redline S; Childhood Adenotonsillectomy Trial (CHAT). A randomized trial of adenotonsillectomy for childhood sleep apnea. *N Engl J Med*. 2013 Jun 20;368(25):2366-76.

<sup>23</sup> Wang R, Dong Y, Weng J, Kontos EZ, Chervin RD, Rosen CL, Marcus CL, Redline S. Associations among Neighborhood, Race, and Sleep Apnea Severity in Children. A Six-City Analysis. *Ann Am Thorac Soc*. 2017 Jan;14(1):76-84.

<sup>24</sup> Quante M, Khandpur N, Kontos EZ, Bakker JP, Owens JA, Redline S. A Qualitative Assessment of the Acceptability of Smartphone Applications for Improving Sleep Behaviors in Low-Income and Minority Adolescents. *Behav Sleep Med*. 2019 Sep-Oct;17(5):573-585.

exist. But only 73 were related to sleep self-management. Of those, only 14 both allowed patients to enter personal data and collected data through sensors.<sup>25</sup> Therefore, more sophisticated sleep-related apps are lacking that harness AI to guide patients through their sleep journey. Although there are not currently any sleep related apps similar to mySV, the literature does support its use in terms of enhanced patient outcomes and reduced healthcare system cost. The Spanish CONNECARE Horizon 2020 project included 48 elderly patients suffering from chronic obstructive pulmonary disease (COPD) or heart failure who utilized a patient-management app, a set of integrated sensors through a Fitbit device, and a web-based platform to integrate data app-collected data with healthcare professional evaluation. Their functional improvements and healthcare facility utilization over 6 months was compared to similar individuals receiving usual, non-mHealth based care. Participants in the mHealth arm showed some greater improvement in functional outcomes, but cost savings was even more apparent. **MHealth users had 57% fewer unplanned visits with health care providers and 50% fewer hospital admissions related to COPD or heart failure.** The authors estimated that each patient in the usual care arm cost that healthcare system \$3243.56, compared to \$2482.17 per patient for individuals using the mHealth platform.<sup>26</sup> Data from the Dartmouth Hitchcock Health System shows high acceptance and cost savings among users of a similar mHealth app for chronic disease management.<sup>27</sup>

These findings are important because they show (1) cost savings (with per capita cost being the third part of medicine's triple aim) and (2) *healthcare utilization* savings. First, the per capita cost was significantly reduced. Utilizing the costs data above, a \$761.39 (or 23.5%) savings was achieved over the 6 months of the study. As noted above, the AASM Report revealed that *diagnosed* OSA cost the United States \$12.4 billion in 2015 (\$2,105 per capita). If mySV could reduce health care cost for those individuals by about the same percentage as noted in the Spanish cohort, \$2.9 billion (\$495 per capita per year) could be saved. Of course, this modeling does not take into account the \$149.6 billion total cost for *undiagnosed* individuals. One might expect saving with this group to be much greater. Second, the study demonstrated significant impact on population health with healthcare utilization cut by about half in those participants utilizing the mobile platform. Applying this finding to the OSA population, another chronic disease with significant cardiovascular comorbidities, a similarly integrated mHealth app such as mySV could substantially reduce routine visits and contacts with the sleep clinic.

But could cutting down on sleep clinic contacts reduce sleep practitioner reimbursement? We estimate that sleep practitioners are ideally positioned to *benefit* from mySV. Sleep

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<sup>25</sup> Choi YK, Demiris G, Lin SY, Iribarren SJ, Landis CA, Thompson HJ, McCurry SM, Heitkemper MM, Ward TM. Smartphone Applications to Support Sleep Self-Management: Review and Evaluation. J Clin Sleep Med. 2018 Oct 15;14(10):1783-1790.

<sup>26</sup> de Batlle J, Massip M, Vargiu E, Nadal N, Fuentes A, Ortega Bravo M, Miralles F, Barbé F, Torres G; CONNECARE-Lleida Group. Implementing Mobile Health-Enabled Integrated Care for Complex Chronic Patients: Intervention Effectiveness and Cost-Effectiveness Study. JMIR Mhealth Uhealth. 2021 Jan 14;9(1):e22135.

<sup>27</sup> Petersen CL, Weeks WB, Norin O, Weinstein JN. Development and Implementation of a Person-Centered, Technology-Enhanced Care Model For Managing Chronic Conditions: Cohort Study. JMIR Mhealth Uhealth. 2019 Mar 20;7(3):e11082.



practitioners with excess clinical capacity can partner with various access points listed above (primary care offices, community clinics, etc.) to bring more potential patients into their practice through mySV. Other, busier sleep practitioners looking to optimize reimbursement having already-full schedules also stand to gain. As demonstrated above, patients engaging with mHealth tend to utilize health care services less, but this finding does not imply fewer economic resources will flow to sleep practitioners. On the contrary, mySV would substantially reduce more routine, less reimbursable clinical workload and allow sleep practitioners to focus on more complex (and more highly reimbursable) patient management. For instance, the app can shepherd a patient through routine home sleep apnea testing with minimal practitioner involvement for straightforward OSA diagnoses. However, if test results are equivocal or particularly concerning, sleep practitioners will be engaged for polysomnography testing and interpretation. Abnormalities on CPAP downloads will also engage practitioners in potentially higher billing visits with patients or, again, more advanced testing. Thus, sleep practitioners could better perform – and bill – at the “top of their license” on a more consistent basis given their available clinical time. Please refer to **Appendix C**.

Therefore, mySV is an inclusive, patient-centered approach to engage large populations on the road to sleep health while also enhancing sleep practitioner reimbursement. It embodies medicine’s triple aim by improving patients’ experience of care while reducing per capita cost to the healthcare system; extrapolating from AASM data above, if just 10,000 individuals use mySV to address their latent OSA, up to \$42,610,000 could be saved. There is data that diverse populations (young and old) are receptive to such apps, and an advanced tool such as mySV does not currently exist. Additionally, mySV represents a more advanced effort to provide personalized care for every patient. The characterization of the biological characteristics of an individual or specimens from an individual to tailor and deliver therapeutics and diagnostics for patients represents Precision Medicine.<sup>28</sup> Genomics, pharmacogenomics, and metabolomics are some examples of precision medicine tools currently available.

Although today precision medicine and personalized medicine may be used interchangeably, they are unmistakably different. Precision medicine is essentially a roadmap to achieving personalized medicine. Precision medicine incorporates biological tools and technology to increase information to provide personalized medicine, all in pursuit of high-value care. This information includes personomics, the study of the person–the patient– in front of the clinician.<sup>29,30</sup> Personomics is essential to delivering personalized medicine by understanding the multi-faceted dimensions of the patient being evaluated. Personomics involves learning the patient's goals, their concerns, what past experiences they have had, their financial support, their networks, etc., the things that are important for engaging the patient in care. While these things have always been important in healthcare,

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<sup>28</sup> Khalyfa A, Gileles-Hillel A, Gozal D. The Challenges of Precision Medicine in Obstructive Sleep Apnea. *Sleep Med Clin*. 2016 Jun;11(2):213-26. doi: 10.1016/j.jsmc.2016.01.003.

<sup>29</sup> Ziegelstein RC. Personomics and Precision Medicine. *Trans Am Clin Climatol Assoc*. 2017;128:160-168.

<sup>30</sup> Ziegelstein RC. Perspectives in Primary Care: Knowing the Patient as a Person in the Precision Medicine Era. *Ann Fam Med*. 2018;16(1):4-5.

the landscape has changed dramatically, and as a result, patients may not feel as connected to their physician. Moreover, there is much more information (e.g., outside records, changes in weight over time, recent recommendations from a primary care provider, etc.) available about patients that, many times, the clinical team may not have access to readily. mySV allows the healthcare team and the patient and their family (members of the interprofessional healthcare team) together with the most current health information from various sources to deliver personalized, high value care. Further mySV provides customization with patient preferences, interests, while allowing them to receive up to date information and education regarding their health and wellness that can be shared with family members. mySV allows plugins with a variety of existing (and future) platforms, apps, devices to capture health information that can be stored and tracked for trends and potential risks or concerns the patient which can be shared with the clinical team and easily integrated into the medical record with the click of a button saving precious time for the patient-physician interaction.

Now is the time for patients, potential patients, caregivers, and sleep practitioners across America to receive their invitation to visit mySV.