

ITERATING THE BUSINESS MODEL IN A NASCENT MARKET: ALIVECOR

“It’s hard to evolve from being a hardware to a services company and embrace both the business-to-business-to-consumer and direct-to-consumer culture. It’s hard to be good at enterprise sales and make delightful products for the consumer. I think those big themes have been challenging for many companies, not just AliveCor. But being a first mover has benefitted AliveCor because they have had the funding and brand loyalty to successfully embrace different business models.”

– Jacqueline Shreibati, MD, Former CMO, AliveCor

AliveCor is a pioneer in personal electrocardiogram technology (ECG). It was one of the first companies to leverage digital technology to allow anyone with a smartphone to record and view their own heart rhythms. While this capability appealed to multiple users, including cardiologists, researchers, and patients with concerns about their heart health, it took time for the market to mature. And when it did, a host of competitors in the consumer space made it difficult for AliveCor to sustain its first-mover advantage. Fortunately, the company has had a steady influx of financing, and a willingness to evolve its business model in order to optimize and sustain growth.

Background

For decades, portable event monitors have been used to record electrocardiograms (ECG) for non-hospitalized patients. These graphic representations of the heart’s electrical activity could be transmitted over the telephone as sound, then converted back into a graphic on the receiving end. In 2010, David Albert, MD, the former chief clinical scientist of GE’s cardiology division, digitized that process.

Working with scientists Kim Barnett and Bruce Satchwell, Albert built a wireless, single-lead ECG into an iPhone carrying case. The case had two electrodes on the back. To generate a reading, the patient simply placed the case on their chest or held it with two hands. The reading was then transmitted wirelessly to the iPhone and displayed graphically on the screen. The data also could be securely stored and/or downloaded onto another device or platform, allowing a remote provider to access and interpret the information.¹

To help demonstrate the prototype, Albert made a YouTube video.² It went viral, capturing the imagination of early technology adopters who saw the iPhone ECG as an example of how new digital health tools could change the way care was delivered, making it more accessible and less expensive.

Invented as a hobby rather than intended as a commercial product,³ the iPhone ECG seemed initially like a hammer in search of a nail. Catalyzed by the video, though, specific uses quickly emerged. First responders could use it to rapidly screen for rhythm abnormalities in the field – even in tight spaces – and transmit that information back to emergency room doctors. Physicians could employ it in their practice as a quick and inexpensive way to assess cardiac rhythm. And cardiac patients – especially those diagnosed with or at risk for atrial fibrillation (AF), the most commonly occurring arrhythmia and one that carries a five-fold increased risk of stroke⁴ – were interested in it as monitoring tool that could help them take control of their health.⁵

The video generated funding offers that launched AliveCor as a business in 2011.⁶ However, even as the buzz got louder, there was a critical question facing the new company: how would it make money?

The Initial Business Model

As a first mover, AliveCor had to consider several external factors in determining its business model.

The first was technology adoption. When the company came into being, smartphones were far from ubiquitous. “For the first handful of years, AliveCor was in a market where only half the adult population had a smartphone,⁷ including only 20-30% of older adults, the population most likely to have atrial fibrillation,” said Jacqueline Shreibati, a general cardiologist and health services researcher who was the chief medical officer at AliveCor from 2016 to 2019.⁸

Albert, who became the company’s first chief medical officer, was an experienced medical device innovator. He knew it would take time for physicians to become familiar with the technology and that winning their confidence would depend on having published research to demonstrate its effectiveness. This data would also be central to gaining regulatory approval from the US Food and Drug Administration (FDA). Accordingly, early uses of the technology were focused on collecting and publishing data that verified the product’s accuracy, performance, and clinical value. To generate data as quickly as possible, AliveCor started with veterinary applications and research projects that involved performing AF screenings in Australia and the UK.

“The team was scrappy and looking for different ways to get feedback from the clinical community. And they thought quite broadly about what that feedback meant,” said Shreibati.

The second factor that informed the business model was regulatory approvals. Leveraging its early research, AliveCor won its first FDA clearance – which allowed it to market the heart monitor exclusively to physicians – in 2012.⁹ “Early physician adopters were AliveCor’s first real customer,” said Shreibati. Fortunately for AliveCor, this group was technology oriented. “Electrophysiologists (arrhythmia specialists) were especially interested in incorporating the ECG technology into their research on the evaluation and management of arrhythmias,” she described. “It was an exhilarating time for this tech-friendly audience.”

The company decided to sell the technology to interested physicians for a one-time, flat-fee payment. In addition to using the smartphone ECG in their practices and prescribing it to patients, physician researchers also became enamored with the device. “For about \$200 – the cost of the device at the time – you could record as many ECGs as you wanted in order to investigate the benefits of screening for AF, or as a monitor for palpitations,” said Shreibati. “Clinical researchers liked having this cost-effective tool at their disposal.”

For the next two years, AliveCor focused on meeting the needs of cardiologists and academic medical centers, building brand recognition, and engendering deep customer loyalty. They also adapted the technology to be compatible with the Android operating system, ultimately developing a credit card-sized reader (later named KardiaMobile) that could be clipped to the back of various brands of smartphones.

The Shift to a Direct-to-Consumer Model

In 2014, AliveCor received FDA clearance to sell its heart monitor over-the-counter.¹⁰ This launched a new direct-to-consumer marketing effort based on the premise that the technology could provide people with suspected or diagnosed heart conditions, or those at risk of heart conditions, with the ability to track their heart health easily and affordably.

According to Shreibati, the AF patient advocate community¹¹ helped lead the adoption of the technology. “These communities are very focused on understanding their heart and embracing ownership of their data,” she said. “Over the next few years, sales increased as consumers became increasingly interested in the

ability of digital health products to help them proactively manage their overall health and facilitate prophylactic care.”

However, the FDA clearance imposed an important constraint that affected the company’s ability to grow in the consumer market. While AliveCor could sell directly to consumers, the FDA required that the first ECG recorded had to be reviewed and interpreted by a board-certified cardiologist. “This was a ceiling in terms of scale,” said Shreibati. “There aren’t enough cardiologists willing or able to reviewing ECGs for a start-up that could potentially support millions of users.”

To accommodate this requirement, AliveCor charged consumers a one-time hardware sale of the monitor (\$199) that was inclusive of the first ECG review. They also offered users the ability to pay for additional ECG interpretations. Later, AliveCor developed and obtained regulatory clearance for algorithmic analyses and ECG display that were purely over-the-counter; meaning they did not require “unlocking” by a board-certified cardiologist.¹²

The company received multiple FDA clearances for AI-based analyses of the ECG, including atrial fibrillation in 2014.¹³ The AF-detection algorithm reflected AliveCor’s hopes of becoming services company that could leverage patient data, machine learning, and algorithms to analyze ECG data. “We’re building the company strategy based on the idea that ultimately the device itself becomes a commodity item,” said 2014 company CEO Euan Thomson. “Ultimately, our strategy is not to build the company off the device itself, the strategy is to build the company off the analytics and interpretation services.”¹⁴

The Consumer Market Matures...and So Does the Competition

Within a few years, AliveCor had a robust market for its consumer ECG products, with broad smartphone adoption (over 75% of US adults owned a smartphone in 2016),¹⁵ an educated and loyal physician cohort, empowered patients, and a portfolio of regulatory clearances. Even though there was and still is no formal recommendation from the US Preventative Services Task Force to pursue screening in asymptomatic individuals, “...by that point, most physicians realized that when someone experiences a little fluttering in their chest, for example, once a year during the holidays, having an ECG at home could be a reasonable option to ascertain the relationship between a person’s heart rhythm and their symptoms,” said Shreibati. “That was something that AliveCor spent the first handful of years educating physicians about.”

But this progress also advantaged fast-moving competitors, including Apple, Withings, Samsung, and FitBit, all of whom capitalized on the R&D work performed by AliveCor. Another concern for the company was the fact that they had reduced the price of the KardiaMobile device itself to around \$100. “Generally, in consumer electronics, the cost for the customer goes down over time,” said Shreibati. “And only 4-6 million US adults have AF, so the company had to start thinking about other ways to drive revenue and grow the company.”

To accomplish this AliveCor embarked on a cadence of regular product iterations, including enhanced software applications and new use indications, hardware, services, and partnerships. Examples of these offerings included an education service that provided users with all of the tools needed to “fully participate in their own cardiac health”;¹⁶ a platform to screen for elevated potassium;¹⁷ hardware that paired with the Apple Watch to record and display an ECG¹⁸ (before Apple developed this as a native capability); a 6-lead, higher-accuracy device called the KardiaMobile 6L;¹⁹ and partnership with Mayo clinic to develop an algorithm to detect long QT syndrome (a heart rhythm condition that can lead to fainting, seizures, or death),²⁰ among many others.

However, this constant technology iteration was expensive. “If you’re doing anything within the consumer wearables space, you’re expected to put something new on the market annually, if not more frequently,” said Shreibati. “But it’s much harder to do that when the product is regulated. For example, new devices like the KardiaMobile 6L are years in the making, not only to get the form factor right, but to go through the FDA clearance process.”

Some of the evolutions also had uncertain value. “The more information you provide, the more you need to involve experts to help consumers use and interpret the data,” said Shreibati. “It’s like a Starling curve

where giving people more and more data is helpful to a point, but then it drops off because it's not as understandable or actionable.”

Despite these concerns, AliveCor continued to experience success on the consumer front, combining hardware sales with a \$9.99 per month subscription service to help users interpret their heart data and otherwise manage their heart health at home.²¹ Initially, the heart monitor was sold only the AliveCor website, although the bulk of consumer sales later shifted to Amazon. “The company’s consumer-derived revenue gave the team the opportunity to be innovative with their healthcare strategy,” noted Shreibati.

Growing B2B2C

Even as AliveCor focused its efforts on selling directly to consumers, it had maintained its customer base of healthcare providers and researchers. And this audience represented another avenue for growth. The cardiology and electrophysiology communities maintained tremendous brand loyalty to AliveCor. “It was still the favorite tool for population-based arrhythmia research. And physicians felt comfortable recommending KardiaMobile – which supports Android and iOS--to their patients because there was less perceived conflict of interest than promoting a single brand like Apple Watch,” described Shreibati.

However, to more widely incorporate KardiaMobile into their research programs and practices, medical centers needed a web-based platform that would allow them to securely review large amounts of ECG data. To better understand the need, a Cleveland Clinic cardiac electrophysiologist, Khaldoun Tarakji, invited AliveCor to send engineers and product managers to observe the electrophysiologists’ clinical care workflow. The experience was “eye-opening” for the AliveCor team, who subsequently conceived the enterprise KardiaPro web-based platform in 2017.²²

“AliveCor built the KardiaPro in direct response to key opinion leaders in the cardiology space saying, ‘Look, your product works. It’s been on the market for a few years. Now my patients have access to smartphones that can support KardiaMobile. So we’d like to have a way to get the data from patients at home and incorporate it into our research and treatment plans,” Shreibati added. The software is free for physicians to use.

In the last few years, AliveCor has taken a broad and adaptive approach to reimbursement models. The KardiaPro platform accommodates a variety of CPT codes, introduced in 2018, that physicians can use to bill for remote patient monitoring. In 2021, AliveCor acquired an independent diagnostic testing facility (IDTF), which will allow the company to bill directly for a full suite of cardiac monitoring services, including use of KardiaMobile 6L. The acquisition of an IDTF “sets AliveCor on a course to becoming the premier provider of end-to-end cardiac diagnostic support,” said Priya Abani, current company CEO.²³

Reflecting...and Looking Ahead

Looking back at how AliveCor’s business models have evolved over the last decade, it is evident that start-ups need to be responsive and adapt to ever-changing trends in health technology adoption, clinical workflows, medical research, and reimbursement.

While growing the company and staying ahead of the competition hasn’t always been easy, the global ECG device market AliveCor helped build was recently estimated to reach a market value of \$7,271 million by 2027, fueled in part by the growing geriatric population, increasing incidence of cardiovascular disease, and demand from emerging economies with strong healthcare infrastructure.²⁴ The company has moved into multiple international markets, including China and India.

Shreibati believes that the future is bright for AliveCor because the company has demonstrated resilience and ingenuity, time and time again. “Many companies struggle to self-reflect and course correct, especially in the face of competition,” she said. “But digital health companies like AliveCor will succeed because they are committed to providing physicians, patients, and consumers with an accessible and valuable health experience. And that’s ultimately what matters at the end of the day.”

Key Insights:

- **Do the Research**

For digital health companies to get physician buy-in, published research is key. According to AliveCor founder Dave Albert, “Don’t forget this is medicine... you need to prove clinical value. Clinical research does slow you down – it’s a challenge. But the world isn’t going to give you a pass...if you want to help patients, then you need to do it.”²⁵

- **Recognize the Value of Regulatory Clearance**

Digital health innovators often wonder if they should pursue regulatory clearance. According to Shreibati, the answer is a resounding yes. “It’s like a magic word – it gives everyone in the room some sense of security. Regulatory clearance sets a bar for the claims a company can make about a device, providing physicians and consumers some assurance of safety and effectiveness. It’s doesn’t guarantee real-world health outcomes, but it is a decent first step. For companies developing software as a medical device (SaMD), regulatory clearance can unlock opportunities to incorporate an algorithm into other platforms and hardware.”

- **Listen to Your Customers**

By listening to its physician consumers and investing the time and effort required to understand their needs and workflow, AliveCor was able to build a responsive enterprise software platform that facilitated continued professional use of the KardiaMobile hardware and reinforced its strong partnership with providers.

¹ Satish Misra, “A new iPhone peripheral that monitors single lead EKG is generating a lot of buzz – is it all deserved?” iMedicalApps + MedPage Today, January 4, 2011, <https://www.imedicalapps.com/2011/01/iphone-ekg-monitor-peripheral-medical-healthcare-app/> (October 15, 2021).

² Brian Buntz, “Ahead of His Time,” Medical Device & Diagnostic Industry Online, January 3, 2012, <https://www.mddionline.com/news/ahead-his-time> (October 16, 2021).

³ Brian Buntz, “Ahead of His Time,” Medical Device & Diagnostic Industry Online, January 3, 2012, <https://www.mddionline.com/news/ahead-his-time> (October 16, 2021).

⁴ “AliveCor’s Heart Monitor for iPhone Receives FDA Clearance,” AliveCor press release December 3, 2012, https://www.kardia.com/press/press_release/alivecors-heart-monitor-for-iphone-receives-fda-clearance/ (October 16, 2021).

⁵ Brian Dolan, “Interview: iPhoneECG Ready for Android, Too,” MobiHealthNews, January 17, 2011, <https://www.mobihealthnews.com/9955/interview-iphoneecg-ready-for-android-too/> (October 15, 2021).

⁶ Brian Dolan, “iPhone ECG developer AliveCor Raises \$3 Million,” MobiHealthNews, August 2, 2011, <https://www.mobihealthnews.com/12224/iphone-ecg-developer-alivecor-raises-3-million/> (October 17, 2011).

⁷ Aaron Smith, “Smartphone Ownership 2013,” Pew Research Center, June 5, 2013, <https://www.pewresearch.org/internet/2013/06/05/smartphone-ownership-2013> (October 22, 2021).

⁸ All quotations are from interviews conducted by the author unless otherwise cited.

⁹ “AliveCor’s Heart Monitor for iPhone Receives FDA Clearance,” AliveCor press release December 3, 2012, https://www.kardia.com/press/press_release/alivecors-heart-monitor-for-iphone-receives-fda-clearance/ (October 16, 2021).

¹⁰ “AliveCor Receives FDA Over-the-Counter Clearance for its Heart Monitor,” AliveCor press release February 10, 2014, https://www.kardia.com/press/press_release/alivecor-receives-fda-over-the-counter-clearance-for-its-heart-monitor/ (October 16, 2021).

¹¹ Facebook Atrial Fibrillation Support Forum – Public Group at <https://www.facebook.com/groups/AtrialFibrillationSupportForum/> (October 26, 2021).

¹² US FDA letter to AliveCor re: 510(k) clearance, April 9, 2019, open with Adobe Acrobat after downloading https://www.accessdata.fda.gov/cdrh_docs/pdf18/K183319.pdf/ (October 26, 2021).

-
- ¹³ Jonah Comstock, "AliveCor Gets FDA Clearance for Atrial Fibrillation Algorithm," August 21, 2014, <https://www.mobihealthnews.com/35973/alivecor-gets-fda-clearance-for-atrial-fibrillation-algorithm> (October 15, 2021).
- ¹⁴ Fierce Biotech, "AliveCor – 2014 Fierce 15," October 1, 2014, <https://www.fiercebiotech.com/special-report/alivecor-2014-fierce-15> (October 17, 2021).
- ¹⁵ Aaron Smith, "Record Shares of Americans Now Own Smartphones, Have Home Broadband," Pew Research Center, January 12, 2017. <https://www.pewresearch.org/fact-tank/2017/01/12/evolution-of-technology/> (October 22, 2021).
- ¹⁶ "AliveCor Continues to Improve Its Service Offerings," AliveCor press release March 18, 2014, https://www.kardia.com/press/press_release/alivecor-r-continues-to-improve-its-service-offerings/ (October 16, 2021).
- ¹⁷ "FDA Designates AliveCor's Bloodless Hyperkalemia Test a 'Breakthrough Device,'" AliveCor press release September 10, 2018, https://www.kardia.com/press/press_release/fda-designates-alivecors-bloodless-hyperkalemia-test-a-breakthrough-device/ (October 17, 2021).
- ¹⁸ "FDA Clears First Medical Device Accessory for Apple Watch," AliveCor press release November 30, 2017, https://www.alivecor.com/press/press_release/fda-clears-first-medical-device-for-apple-watch/ (October 17, 2021).
- ¹⁹ "FDA Grants First Ever Clearance for Six-Lead Personal ECG Device," AliveCor press release May 13, 2019, https://www.kardia.com/press/press_release/fda-grants-first-ever-clearance-for-six-lead-personal-ecg-device/ (October 18, 2021).
- ²⁰ Terri Malloy, "Mayo Clinic Research Yields Breakthrough in Mobile Determination of QT Prolongation," Mayo Clinic News Network, <https://newsnetwork.mayoclinic.org/discussion/mayo-clinic-research-yields-breakthrough-in-mobile-determination-of-qt-prolongation> (October 26, 2021).
- ²¹ Mallory Hackett, "AliveCor Adds ECG Subscription Service to its Product Line," MobiHealthNews, July 9, 2020, <https://www.mobihealthnews.com/news/alivecor-adds-ecg-subscription-service-its-product-line> (October 16, 2021).
- ²² "AliveCor Unveils First AI-Enabled Platform for Doctors to Improve Stroke Prevention Through Early Atrial Fibrillation Detection," AliveCor press release March 16, 2017, https://www.alivecor.com/press/press_release/alivecor-unveils-first-ai-enabled-platform-for-doctors/ (October 17, 2021).
- ²³ "AliveCor Acquires Cardiolabs and Sets the Stage for the Launch of Advanced Ambulatory Monitoring Services," AliveCor press release June 2, 2021, https://www.kardia.com/press/press_release/alivecor-acquires-cardiolabs-and-sets-the-stage-for-launch-of-advanced-ambulatory-monitoring-services/ (October 26, 2021).
- ²⁴ "ECG Devices Market Value Estimated to Reach US \$7,271.2 Million by 2027," Acumen Research and Consulting press release, February 15, 2021, <https://www.globenewswire.com/en/news-release/2021/02/15/2175571/0/en/ECG-Devices-Market-Value-Estimated-To-Rreach-US-7-271-2-Million-By-2027-Acumen-Research-And-Consulting.html> (October 17, 2021).
- ²⁵ Satish Misra, "Interview with AliveCor Founder Dr. Dave Albert: Mobile Health Research & Physician Entrepreneurs," iMedical Apps + MedPage Today, September 17, 2015, <https://www.imedicalapps.com/2015/09/alivecor-interview-dave-albert/> (October 17, 2021).