Contact:

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PRODUCT:

BaroHawk™ Blood Pressure Management System for vasopressor titration. Replaces the poorly implemented clinical process of manually adjusting the IV medication infusions with an automated, user-friendly system. Proven highly effective in human clinical studies and vastly superior to management by hand.

LOCATION: Newport Beach, CA

NUMBER OF EMPLOYEES: 5 part-time presently, $0 payroll, all working for equity. CEO will transition to 100% time after fundraising round.

CURRENT INVESTORS: Founders, NIH grant, equity for services exchange with MODO medical design, $180k convertible notes.

COMPANY: Delaware C-Corp

PATENTS: 3 provisional Patents owned by company covering software, mechanical design, and user interface. One patent licensed from UCI covering algorithm safety aspects. Additional utility patents to be filed Q1 2021.

FINANCING SOUGHT: $500k

USE OF FUNDS:

- Filing of additional utility patents
- Complete pre-manufacturing design
- Establish manufacturing partnership

CONTEXT: Global aging population, leading to more surgeries and critical illness. Shortages in healthcare workers. Rising healthcare costs. Lack of standardization and failure to implement established protocols leading higher to patient mortality/complications and high expenses. Hospitals and clinicians desperately looking for solutions which increase efficiency and effectiveness.

PROBLEM: Blood pressure management within surgery and intensive care is inefficient and often dangerous. Clinicians universally agree that maintaining patients' blood pressure within target (not too high, not too low) is of vital importance. Blood pressure *too low* (hypotension) leads to kidney, heart, and brain injury. Blood pressure *too high* (hypertension) leads to bowel injury, kidney injury, and increased risk of bleeding and stroke. But >75% of critically patients experience hypotension and/or hypertension, and on average spend *40% of time outside of target*. The reason: blood pressure medication (vasopressors) is *hand-adjusted* by the anesthesiologist or bedside nurse, a process which is burdensome, inefficient, and leads to poor results.

SOLUTION: We are completely upending this paradigm – and *dramatically* improving the standard of care – by automating blood pressure management. The BaroHawk system empowers clinicians with total control over targets they set, saving time and energy while achieving greatly improved results. Early clinical studies show we can move patients from 50% time in target to ***>95% time in target***, reducing time in the danger zone by a factor of 10x.

TARGET MARKET: Our target market will be hospitals and health systems, specifically critical care areas where vasopressor infusions are ordered (i.e. operating rooms and intensive care units). Initial hospital targets will be leading centers in United States and Europe, from which we will expand our reach to more centers and more countries in a prioritized phased approach. Initial feedback from potential customers is highly positive and encouraging.

MARKET SIZE: >$2 billion global market potential (independent assessment provided by Key In Strategies), with >$1.1 billion in the US alone. Capture of just 1% of this market at a price point of $50-$100 per disposable will create a sustainable $20-$40M annual revenue stream.

COMPETITIVE ADVANTAGE: At present there is no equivalent or competitive device in this space, only the standard of care manual titration which is clearly inferior. We have a 5-year head start and *significant* advantages over any potential competitors: 1) Direct experience with therapeutic medical device automation from our previous company (Sironis); 2) Significant FDA connections (FDA has previously invited the founders to speak at an FDA-sponsored symposium on closed-loop medical devices; 3) Deep credibility in anesthesia & critical care medical literature on this topic, with dozens of peer-reviewed publications in high-impact anesthesia journals. 4) The CEO personally developed the only other currently FDA-approved closed-loop algorithm for hemodynamic management.

SALES & MARKETING STRATEGY: Strong clinical evidence with KOL (Key Opinion Leader) partners will pave the way for high awareness at conferences and medical forums, with high word-of-mouth excitement; this clinical focus is proven to be the most effective method of driving medical device sales and changing medical practice. Commercial launch will be facilitated by comprehensive marketing plans and our partnership with Critical Alliance LLC as a direct sales channel.

BUSINESS MODEL: Perceptive Medical will supply the BaroHawk system at low cost to hospitals. Revenue will be captured via the disposable component of the system – a sterile tubing cassette that gets used on a per-patient basis (with a possible option for per-day use in the ICU setting to better capture the longer treatment periods). Each disposable's manufacture will be around the $5-$10 range (a high-end estimate), and we are exploring prices starting at $50 (a >80% gross profit margin), potentially as high as $100 per disposable to the consumer. These prices have been tested with consumers and will represent virtually no barrier to use based on cost.

MANAGEMENT

Joe Rinehart *CEO.* MD, Anesthesiologist, former CEO of Sironis Inc. which had successful exit with Edwards Lifesciences in 2014. 50+ clinical publications, multiple startup experience.

Morgan McKeown *Chief of Strategic Marketing*. Long-time med industry veteran. Former head of new-tech discovery at Edwards Lifesciences. Consultant and entrepreneur.

Maxime Cannesson *Chief Medical Officer*. MD, PHD. World-recognized expert in hemodynamic monitoring/ machine learning.

Doug Patton *Chief Design Officer.* 25-year R&D and design veteran with dozens of patents and successful medical devices.

TECHNOLOGY & REGULATORY PATH: BaroHawk will require an FDA IDE study and PMA for approval. We anticipate ≈18 months to complete design & manufacture an IDE-ready device. Assuming IDE submission concurrently with finalizing device design, we would begin a regulatory trial in Q3 2022. With 12-18 months for recruitment and PMA submission, we aim for FDA approval in Q1 2024. Our design & build plan has been developed with the assistance of MODO Medical Design. Long-term we will also explore expanded reimbursement for this system.

POTENTIAL EXITS: Perceptive will pursue commercial sales launch and profitability while actively engaging strategic buyers. Many potential distribution partners and acquisition players have shown interest in this type of technology: *pump manufacturers* (Baxter, BD, etc.) see an opportunity to expand their role into active management while *monitoring companies* (Edwards, ICU Medical, Masimo, etc.) see an opportunity to enter the therapuetics space. Edwards has licensed previous technologies created by the Founders of Perceptive Medical. IPO is another possibility.

GRANT FUNDING: Perceptive Medical has already received $200,000 in non-dilutive NIH funding and is seeking follow-on funding that could exceed $2M. This additional funding, if obtained, will carry the company a long way to commercialization and reduce needs for dilutional equity funding but is not included in any of the financial projections.

SUMMARY: ***Amazing opportunity to truly revolutionize healthcare and improve patient outcomes, with strong likelihood of capturing high financial returns.***