NAVIGATING THE FUNDING DROUGHT

A GUIDE FOR THE MEDICAL DEVICE ENTREPRENEUR

How to meet critical product milestones, increase investor confidence, and accelerate device path to commercialization.

nocturnal

THE COLD REALITY: INVESTMENT MONEY IS HARDER TO COME BY

Securing investment money for medical device startups has become increasingly challenging in the current fundraising environment.

Overall venture funding for medical device companies in 2023 was down 19% compared to 2022 and 25% compared to 2021.

2023
Investment is Down

19% ↓ from 2022

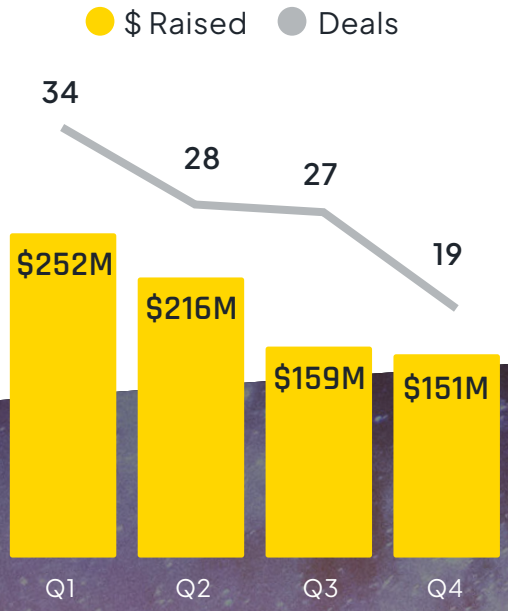
25% ↓ from 2021

First-round deals have contracted at a greater pace, down 18% compared to 2022 and as much as 40% compared to 2021. First-round funding has also contracted each quarter in 2023, from $252 million and 34 deals in Q1 to $151 million and 19 deals in Q4.[1]

Indicating increased adversity to risk on investors' part, first-round financing has shifted away from longer-cycle PMA companies to quicker-to-market 501(k) opportunities.

Beyond the first round, many device startups saw a decline in valuation, with over 30% of Series B or later deals being step-down rounds.

2023 DEALS AND & RAISED



With these forces in play, medical device companies have less room for errors and missteps, which could lead investors to pull out or force a significant down-round. With increased pressure to reduce investor risk, there is greater urgency for meeting product milestones and accelerating commercialization timelines.

[1] Source: HSBC Venture Healthcare Report 2023

nocturnal

RISK REDUCTION PRODUCT DEVELOPMENT STRATEGIES

While economic uncertainty and rising interest rates play a role in the decline of investment across all sectors, medical device companies face some unique challenges that give many investors a longer pause when it comes to committing their capital.

Medical device development— especially for Class II and Class III devices—is a highly complex undertaking that can last years, not months. Going into it, there are many unknowns, and initial assumptions may prove inaccurate as the project unfolds.

According to the Greenlight Guru 2023 MedTech Industry Benchmark Report, pre-market medical device companies misjudge commercialization timelines by an average of 53%.

Prolonged product development cycles, combined with supply chain delays, create significant uncertainty about product cost and time-to-revenue. They also bring a greater risk of changing market conditions, which could adversely impact product viability, competitiveness, and profitability. While none of these factors can be completely removed, there are several ways in which medical device companies can mitigate these risks to ease investor apprehension.

Proactively addressing these concerns can also help startups stretch their raised capital to meet development milestones and reduce the risk of running out of runway.

IN THE FOLLOWING SECTIONS, WE WILL EXPLORE FOUR PROVEN STRATEGIES FOR REDUCING PRODUCT DEVELOPMENT RISKS.

1. Less is more: The power of simplification
2. Jumpstart the learning curve
3. Manage to your goal: What you really need for a POC vs. V1 and V2
4. Milestone-based pricing

nocturnal

1 LESS IS MORE: THE POWER OF SIMPLIFICATION

A common pitfall for medical device startups is the urge to pack as much functionality as possible into the initial version of their implantable device. They overemphasize form factor, longevity, or other common features rather than highlighting their novel technology that offers distinct patient benefits not provided by existing products.

But more is not always better. By concentrating on essential features, developers can optimize time and resources, ultimately leading to a safer path to commercialization.

- **Minimizing regulatory burden:** Complex devices with multiple components and extensive functionality require increased testing and documentation to satisfy regulatory requirements for approval. Novel devices often already face unique regulatory challenges to demonstrate their safety and effectiveness, so it is important to minimize the burden associated with non-critical features.
- **Enhanced reliability:** A simpler design with fewer components and fewer complex functions inherently reduces the likelihood of malfunctions and device-related adverse events. By eliminating unnecessary complexities, we can create more reliable devices that perform their intended functions consistently.
- **Energy efficiency:** The volume of an electronic implant is typically dominated by its battery. By prioritizing simplicity, engineers can design devices that minimize power consumption – reducing battery size, extending battery life, and reducing the frequency of surgical replacements or recharging procedures for patients.
- **Cost-effectiveness:** Simplicity can contribute to cost-effectiveness throughout the device's lifecycle. Simpler designs require fewer materials, reduced assembly labor, and less time to configure and test during the implantation procedure.

2 MANAGE TO YOUR GOAL: WHAT YOU REALLY NEED FOR A POC VS. V1 AND V2

Running out of funds before reaching a market-ready product is a common pitfall for medical device companies. With that in mind, it's crucial t o prioritize and focus on the essentials of what the company needs to prove at each stage in order to raise additional capital.

A Proof of Concept (POC) and subsequent versions of the device serve different purposes, and development efforts for these product iterations should be calibrated to match their distinct goals.

PROOF OF CONCEPT (POC)

- The purpose of a POC is to demonstrate the feasibility of the concept to the investors, which typically doesn't require the full functionality of the product.
- A POC version doesn't need to be approved by a regulatory body, which means that there are no certification and documentation requirements imposed by regulators.
- The POC may be designed and built using components tha t aren't necessarily suitable for long-term use in a medical device but are expedient for demonstration.

VERSION ONE (V1)

- V1 must be fully functional and re ady for use in clinical trials. Its primary goal is to provide sufficient clinical data to validate the efficacy and safety of the device. These results can be leveraged to raise funds for further development to bring the desired product to market.
- V1 must be suitable for submission for regulatory approval, which implies strict compliance and documentation requirements.
- This doesn't mean, though, that V1 needs to have all the bells and whistles. It should be viewed as a Minimum Viable Product (MVP) f or clinical trials. Any functionality that is not required for this purpose should be delay ed for V2.

VERSION TWO (V2)

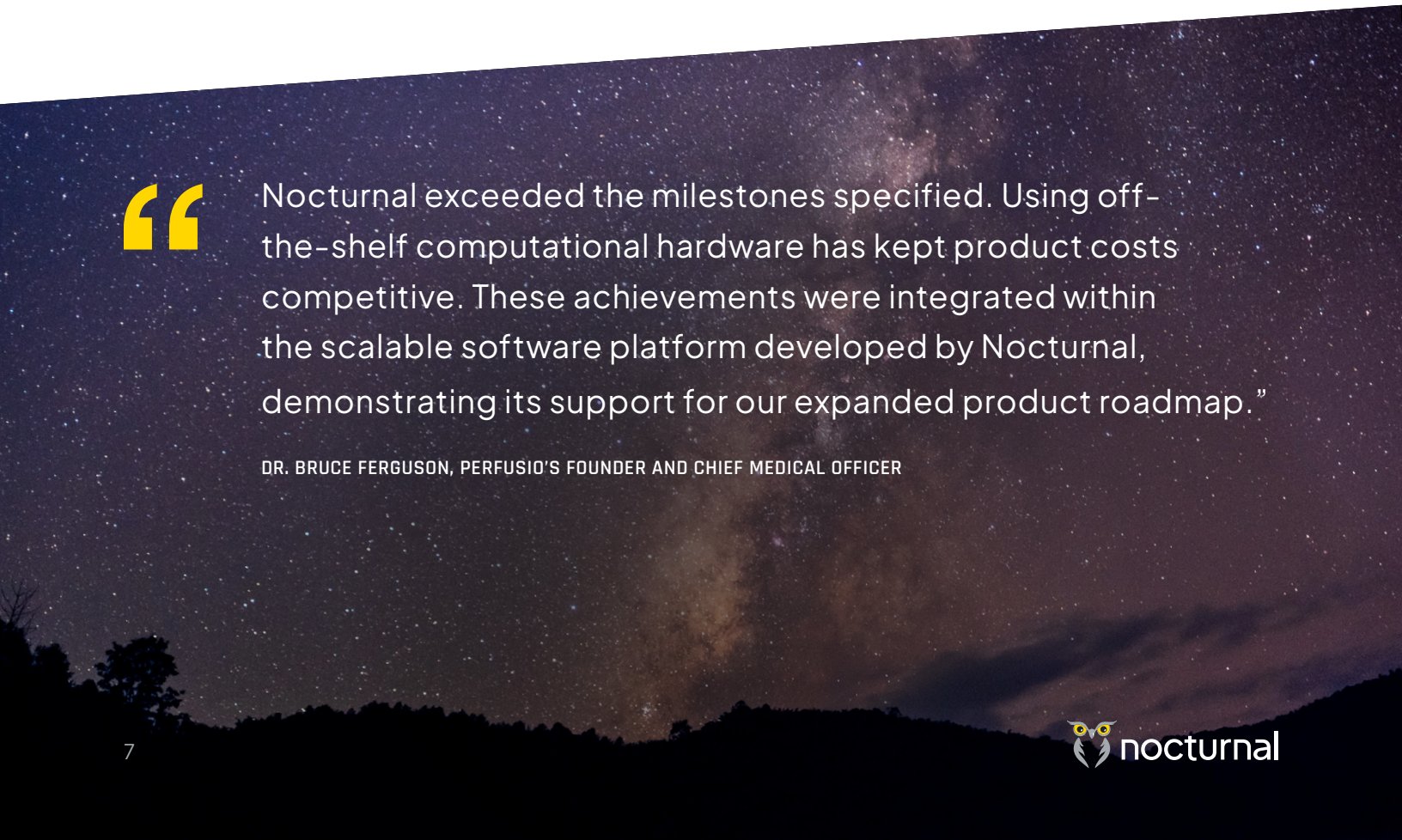
- Ideally, entrepreneurs should develop their V2 in parallel t o V1. This allows for a more efficient timeline, as V2 can be commercialized relatively quickly based on its similarity to V1 and the ability t o leverage clinical data obtained with V1.
- V2 should focus on addressing the shortcomings or less desirable aspects of V1 beyond those necessary for the clinical trials. These could include improvements such as reducing form factor, increasing battery life, or enhancing usability.
- By refining the product based on user f eedback, V2 and subsequent versions can become more attractive to potential customers and investors.

3 JUMPSTART THE LEARNING CURVE

Device startups often get caught up in the notion that their challenge is unique enough to warrant inventing every aspect of the product from scratch. This kind of thinking can add unnecessary cost and time t o the device development.

Reusing existing technologies and know-how doesn't diminish your device's uniqueness. It just allows you to focus on it. It is no t just a shortcut but also a safer path to device commercialization.

The key to success lies in a nuanced underst anding of the different technological components that make up the product architecture and their associated risks. By categorizing these elements into three distinct tiers, startups can focus their innovation efforts where it counts, while utilizing existing assets and expertise to mitigate risks and streamline their path to market.



> "Nocturnal exceeded the milestones specified. Using off-the-shelf computational hardware has kept product costs competitive. These achievements were integrated within the scalable software platform developed by Nocturnal, demonstrating its support for our expanded product roadmap."

DR. BRUCE FERGUSON, PERFUSIO'S FOUNDER AND CHIEF MEDICAL OFFICER

TIER 1: OFF-THE-SHELF COMPONENTS

The key when it comes to off-the-shelf components is to quickly understand whether any can be suitable for the device beyond the proof of concept stage, which is more the exception than the rule for implantable devices.

In the rare cases when off-the-shelf components are suitable, efficiently sourcing these parts while ensuring they meet the required quality and regulatory requirements can yield substantial cost benefits.

TIER 2: TRANSFERABLE IMPLANTABLE DEVICE TECHNOLOGY AND KNOW-HOW

There is a significant body of knowledge that can be applied across different devices. For instance, aspects such as power management, biocompatibility, and miniaturization are common challenges in bo th cardiac and neuromodulation implantable devices.

Elements that can benefit from existing know-how and technologies may include, for example:

- Ultra-low power firmware design
- Ultra-low-power hardware blocks for signal acquisition and power management
- High-density interconnect (HDI) PCB substrate architectures

Understanding where existing technologies and expertise can be leveraged and repurposed in your device can significantly reduce the cost, time, and risk associated with product development.

TIER 3: YOUR SECRET SAUCE

Your device's true innovation lies in your deep understanding of the specific physiology it targets and the distinct features of the therapy it delivers. This is where you want to focus the time and attention of your subject matter experts while leveraging other resources to address areas that are not necessarily proprietary or unique to your device.

4 MILESTONE-BASED PRICING

Milestone-based pricing introduces a novel strategy for medical device development. With projects lasting many months and even years, this model of fixed-cost pricing was initially greeted with skepticism.

When embraced by medical device companies and their product de velopment partners, milestone-based pricing has resulted in significant benefits contributing to lower project risk and accelerated path to commercialization.

Goal alignment and trust
The concept behind milestone-based pricing is to create a symbiotic relationship between the success of the service provider and the client. By setting a f ixed cost for reaching predefined milestones, both parties are incentivized to work efficiently and collaboratively toward the successful and timely completion of the project. This approach establishes a mutual commitment to the project's success and fosters lasting partnerships.

Transparency and control
Milestone-based pricing offers an added layer of financial transparency and control, eliminating the concern over unexpected expenses. This model contrasts sharply with traditional hourly billing systems, which can lead to projects spiraling out of control, causing inflated costs and extended timelines.

Focus on the essentials
This model allows for a clear assessment of how changes will affect the project's budget and timeline, enabling clients to make immediate and informed decisions about project adjustments or enhancements. It allows clients to judiciously weigh the merits of additional investments, enhancing their control over the project's direction and outcomes.

> **"This was my first experience with milestone-based pricing, and I will never go back to hourly billing. Nocturnal's process ensures all parties are fully aligned and incentivized for success, and the results speak for themselves."**
>
> ALEX COOPER, CEO,
> STEALTH MEDICAL DEVICE COMPANY

NOCTURNAL: TURN UNCERTAINTY INTO CONFIDENCE

The current funding environment brings the need for better cash flow control into greater focus.

Nocturnal's VP of Business Development Eyal Dayan hears these concerns in his conversations with clients:

> "The consistent message we hear from early-stage companies is that funding takes longer these days. The framework of a milestone-based pricing project gives them a level of confidence in meeting their critical product milestones without incurring unexpected costs and delays, so they can get to their next round of financing without running out of cash."

Medical device development is complex, and projects often take unexpected turns. It's no surprise that the concept of fixedcost, milestone-based pricing was met with skepticism. But that's where Nocturnal saw an opportunity for a more collaborative and transparent approach.

As Founder and President KC Armstrong explains:

> "Our business model is designed so that our success is intrinsically tied to our client's success. Unlike traditional hourly billing, where there's a risk of projects going off track and leading to increased costs and delays, our fixed-cost pricing model creates a mutual incentive for both parties to stay focused and reach milestones efficiently.
>
> Our clients are often pleasantly surprised when we deliver exactly what we promised without any additional price changes. This not only establishes a strong foundation of trust but also proves that we're as committed to the success of their project as they are."

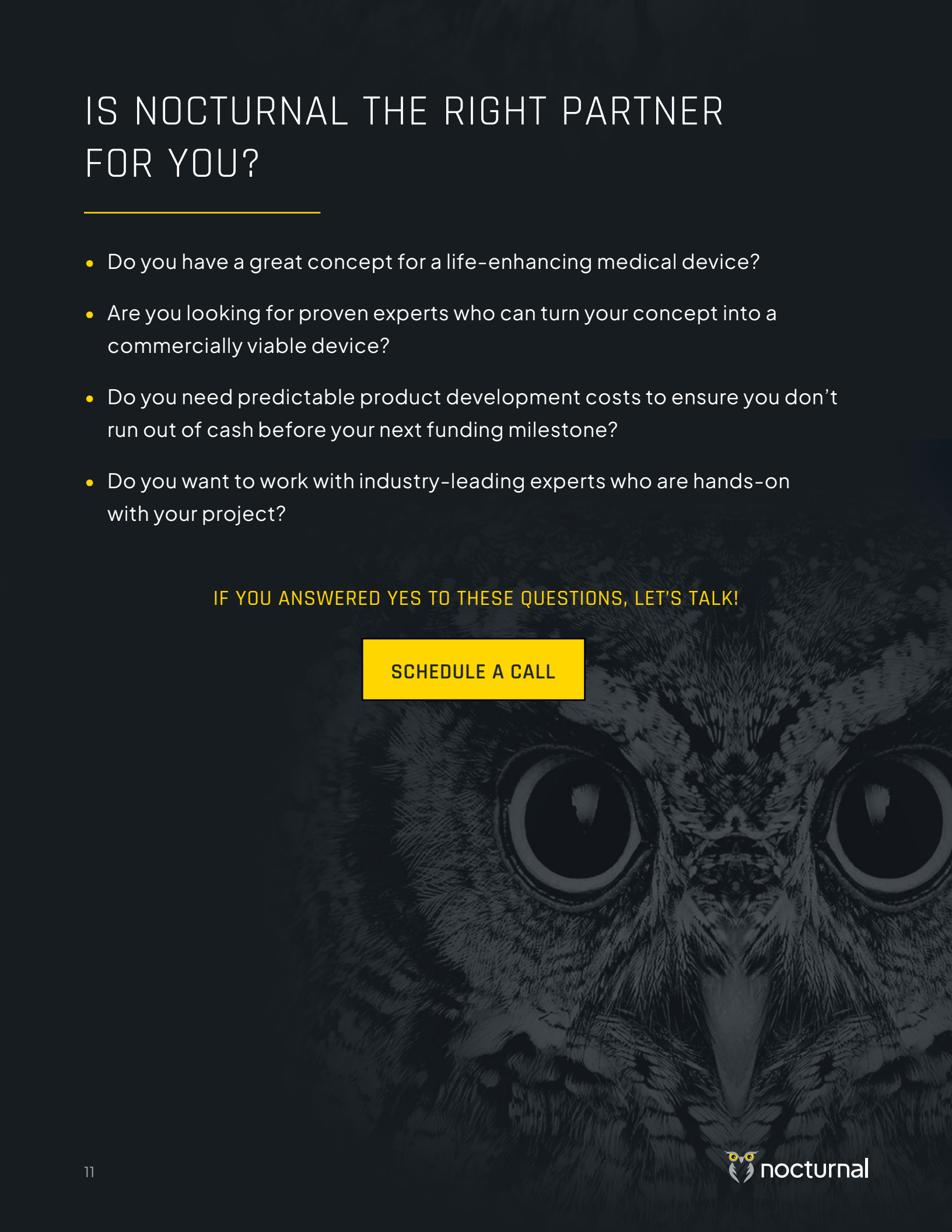
> "Working with Nocturnal has dramatically accelerated our time-to-market. In just one year, Nocturnal took our implantable cardiac monitor from a concept to a fully functional device with a mobile application and secure cloud connectivity."
>
> JAESON BANG, FOUNDER AND CEO, FUTURE CARDIA

IS NOCTURNAL THE RIGHT PARTNER FOR YOU?

- Do you have a great concept for a life-enhancing medical device?
- Are you looking for proven experts who can turn your concept into a commercially viable device?
- Do you need predictable product development costs to ensure you don't run out of cash before your next funding milestone?
- Do you want to work with industry-leading experts who are hands-on with your project?

IF YOU ANSWERED YES TO THESE QUESTIONS, LET'S TALK!

SCHEDULE A CALL



nocturnal

WHY NOCTURNAL?

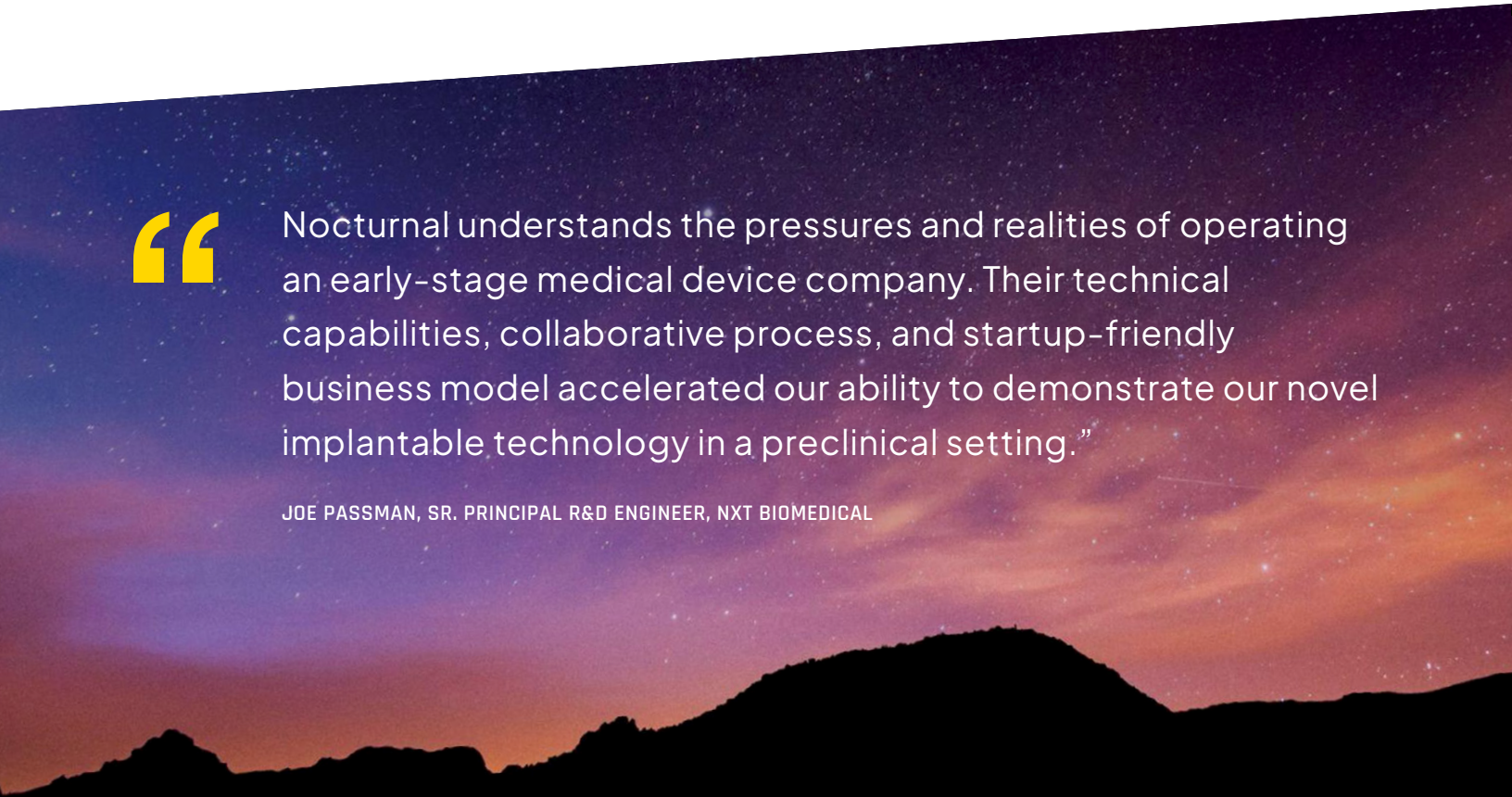
Hard to find expertise in implantable and life-saving devices
"Been there done that" makes a difference when it comes to complex class II and class III device development.

Cash-preserving result-based pricing
Our milestone-based pricing allows you to plan your budget with confidence and draw a viable path to commercial success.

Device-ready building blocks for a quick head start
Using our rich library of hardware designs, software code, and documentation templates — we can get you faster to the finish line while minimizing project risk.

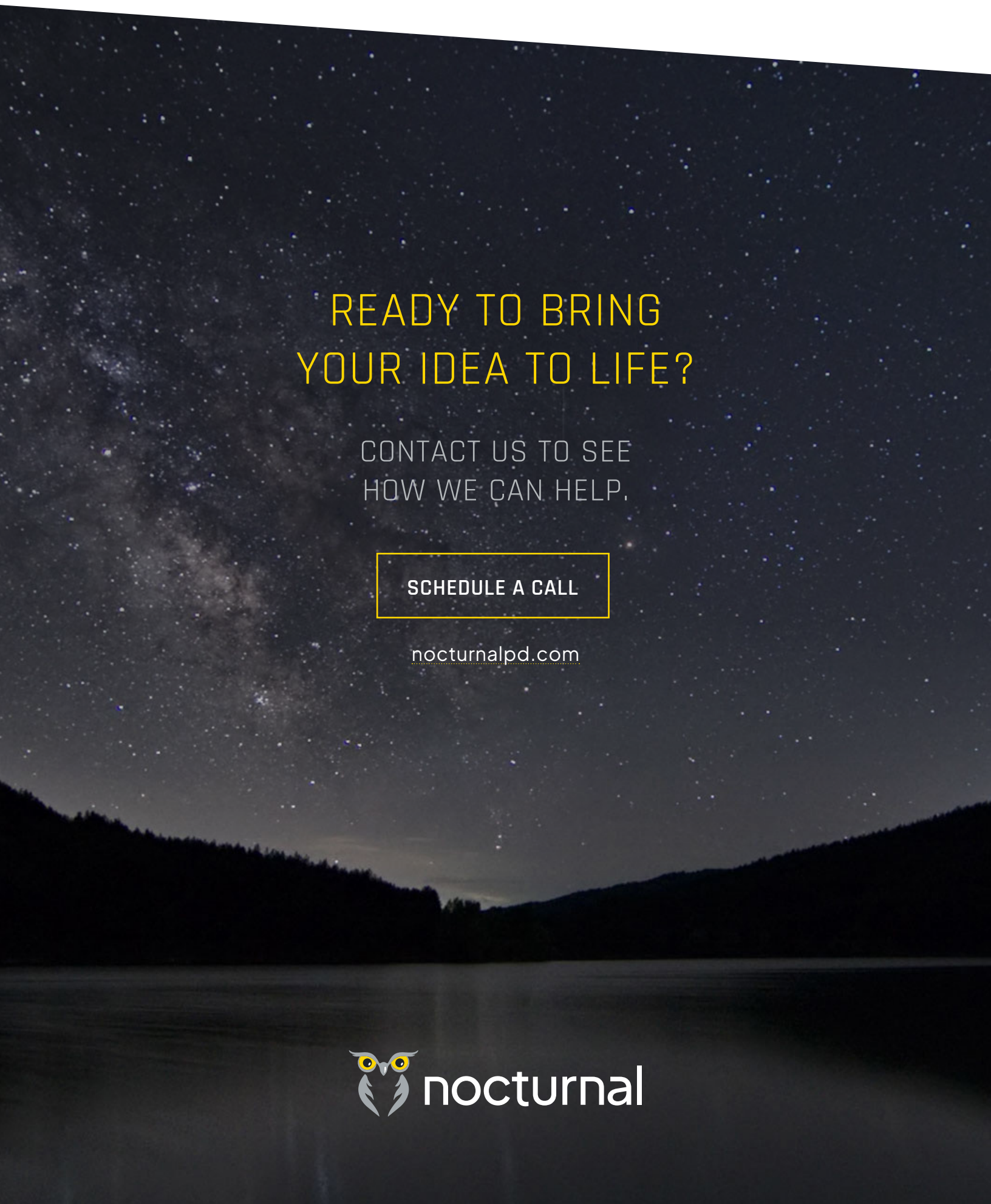
All hands on deck
We are a small team so you always work directly with our best and brightest, because that's all we have.

No surprises. Period.
Complete transparency throughout the project so you always know where you are.



"Nocturnal understands the pressures and realities of operating an early-stage medical device company. Their technical capabilities, collaborative process, and startup-friendly business model accelerated our ability to demonstrate our novel implantable technology in a preclinical setting."

JOE PASSMAN, SR. PRINCIPAL R&D ENGINEER, NXT BIOMEDICAL


READY TO BRING
YOUR IDEA TO LIFE?
CONTACT US TO SEE
HOW WE CAN HELP.
SCHEDULE A CALL
nocturnalpd.com
nocturnal