Silicon photonic biosensors for low-cost, portable, data-rich measurements of hormone biomarkers relevant to women's health and the menopausal transition

Executive Summary for Health Challenge

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What is the unmet need? There have historically been significant gender inequities in healthcare and medical research, with many women's health issues, including symptoms of the menopausal transition, neglected and underfunded. Women's gonadal (sex) hormones can be key indicators of health and impact many conditions beyond fertility, including cardiovascular conditions and neurological disorders. These hormones also fluctuate significantly during the menstrual cycle, requiring frequent monitoring to fully understand the levels and fluctuations. Gonadal hormones are critical during the menopausal transition, with levels of more than 10 hormones linked with perimenopausal symptoms including sleep and mood disruption, brain fog, and hot flashes. These symptoms present a significant societal burden – 25% of people experiencing perimenopause symptoms consider leaving the workforce – but people experiencing them and the physicians treating them have limited tools and data to understand and predict symptoms or monitor and improve the impact of treatment. To provide insightful, impactful data, the ideal monitoring tool would provide quantitative, accurate, and data-rich measurement of at least 4-10 hormones and hormone metabolites, and it would be able to provide these measurements quickly (in minutes) at low cost, in a form factor suitable for people to conveniently use at home at least multiple times per week. This kind of solution does not currently exist: centralized lab-based assays are expensive, slow, and inconvenient for daily testing, while existing point-of-need solutions like lateral flow assays do not provide the required quantitative, accurate, and multiplexed (measurement of multiple hormones) data.

What is being proposed to meet this need? Silicon photonic integrated circuits containing biosensors are well-suited to performing quantitative, accurate, data-rich measurements, and tens to hundreds of sensors can be integrated on a single millimeter-scale chip for multiplexed measurements. They are fabricated with scalable semiconductor manufacturing technologies, facilitating low costs at high volume. A key limitation of these types of sensors has historically been the size and cost of the readout system (e.g., the Genalyte platform for doctors' offices), because an expensive ($40,000-$100,000), bulky tunable laser and light coupling system are required to read out the data, precluding their use for at-home testing applications like hormone monitoring. We have invented a new sensor architecture that addresses this challenge, allowing us to use a tiny (<1 mm), inexpensive (<$1), fixed-wavelength laser for readout. In this project, we propose to validate this new silicon photonic technology, create a bench-scale portable readout system, and demonstrate urine-based detection of an initial panel of two hormone biomarkers relevant to menopause (expandable to tens in the future).

What are the expected outcomes? Through this work plan we will develop our new silicon photonic sensor and quantify its photonic performance metrics (to provide data-rich measurements at 1000× lower cost than traditional photonic biosensors), compare performance with gold-standard measurements, and also quantify detection of two biomarkers relevant to the menopausal transition: pregnanediol (PdG) and follicle-stimulating hormone (FSH). We will also demonstrate a portable system suitable for demonstration at Optica conferences and to collaborators.

What will be the real-world impact of this project? This project will use innovation in photonics to address a critical unmet need in women's healthcare by validating a portable, low-cost technology for decentralized, multiplexed monitoring of hormone markers in urine. With this project, we will build a tool that has the potential to drastically improve health and quality-of-life during the menopausal transition, and also lay the foundation for future development of tests for additional conditions for broader potential impact of the technology on human health.