Artemis Biomedical, Inc.

Non-invasive Blood Glucometry

This slide deck - introductory

- Discussion of the market opportunity
- Founding Team and other key players
- Introduction to our solution
- High-level discussion of our plan; review of progress
- Capitalization

Market Opportunity

- In 2025, 50% of Americans will be diabetic or pre-diabetic
- Other countries are tracking closely behind
- At the root of the physiologic issue: modern behavior is incompatible with human physiology
  - We're not exercising enough
  - We're too good at getting calories or the wrong kinds thereof
  - Result: insulin resistance (aka diabetes)
- How to address this issue: understanding the problem by understanding the blood sugar levels – in each person, accurately enough so that a response can be mustered in real or near-real time
- The major problem: blood sugar testing compliance; no one likes to prick their finger multiple times per day; so they don't, and we end up with this epidemic and all of the co-morbidities (heart disease, kidney failure, neuropathy, loss of vision, loss of limbs, etc)
- Artemis Biomedical Inc: this is our life's work; we have spent decades understanding the physics of measuring the levels of glucose and other compounds in the blood and other tissues non-invasively; thanks to some key technical developments and inventions, we believe that we have the holy grail of blood sugar testing compliance in our sights

Founding Team

- Jeremy Grata, Founder and CEO
  - 30 years of experience in optical physics, applied materials, integrated systems, miniaturization, manufacturing
  - Decades of leading multimillion dollar teams to address glucometry challenges
  - Co-inventor of the core Artemis technology

- Mike Pitsakis, Founder and CTO
  - 35+ years of experience in digital and analog electronics supporting optical systems
  - Decades of developing ISO, FDA/GMP compliant regulatory technology development environments
  - Co-inventor of the core Artemis technology

Key Advisors

- Ralf Marbach, PhD, MBA
  - One of the original key experts in glucose spectrometry
  - CTO and Founder of a spectroscopy venture in parallel space for 15+ years
- Yujie Ding, PhD
  - Johns Hopkins Ph.D. specializing in optoelectronics / laser diodes / quantum electronics; will join Artemis team as FTE
  - Expert in miniaturization and tunable light sources
- Herb Klei, PhD, MBA
  - As the Structural Biology project team leader in Drug Discovery at Bristol-Myers Squibb, brought three drugs to market, atazanavir, dasatinib, and saxagliptin.
  - Parent of a Type 1 diabetic child, committed to addressing the needs of the diabetic community.
- William McPheat, PhD, MBA
  - 25 years experience at AstraZeneca, UK & Sweden, as Principal Scientist, Drug Discovery Project Leader and Team Leader. Experienced in cardiovascular diseases & diabetes. Current state-funded role as Life Science Business Mentor for therapeutic, diagnostic and healthcare device startup companies across Virginia
  - Broadly experienced in preclinical and clinical development and commercialization of healthcare and life science products.
- David Lundmark, Tim Harris, Chip Lion
  - Morrison & Foerster LLP, Palo Alto, CA

Solution

Artists Rendition:
Artemis Device

- With a great deal of R&D in the rear view mirror, and the advancement of several key new technologies and components, we believe that we are onto the holy grail solution for blood glucometry: a small hand-held configuration that reads blood glucose through the skin without impact, finger prick, or instrumental transgression otherwise
- We believe that we will be able to miniaturize our solution to not only be hand-held in geometry, but also to integrate with other common technologies, such as smartphones and smart-watches
- The solution should be manufacturable in reasonably low volume to still meet operating margin targets – and also be priced below conventional finger-prick style glucometry, which will be incredibly disruptive to that embedded market
- The solution will eliminate disposables such as test strips, finger-prick devices / lancets, guillotine lancets
- Very importantly: without the pain, anxiety, and annoyance of the conventional glucometry, 50% of the population will understand their glucose levels in a much deeper manner; pre-diabetic and diabetic patients also will learn significantly more about what behaviors and food intake will impact their glucose levels, how, and with what kind of timing – very clinically relevant
- Everyone knows someone who needs this
- Diabetes generally is well-reimbursed in the US and other healthcare systems; economics should be very easy for the insurers

The Plan, Progress

R&D Prototype Size Device

Artists Rendition: Artemis Device

- Founding, incorporation (Del C corp), clean cap table [Complete]
- Prototype system design [Complete]
- System/method/configuration IP [In Progress]
- Live blood data from prototype system (full IRB) [Month 10]
- Handheld miniaturized functional system [Month 22]
- Manufacturing-ready prototype / final design [Month 31]
- CE-mark for sales in Europe [Month 36]
- FDA approval for sales in US [Month 60]

Capitalization

- Straight forward Delaware C-corp
- Incorporated Oct 2021
- Cap table is clean
- We are in the process of initial meetings to gather starter capital
- Plan is to stay very efficient, have significant progress at the time of A round, get the technology to market
- With initial validation/confirmation of the technology, IP complete, and early team in place, we believe that we will be positioned to have interesting discussions with strategics given the size of the market

Thank you

Market Opportunity

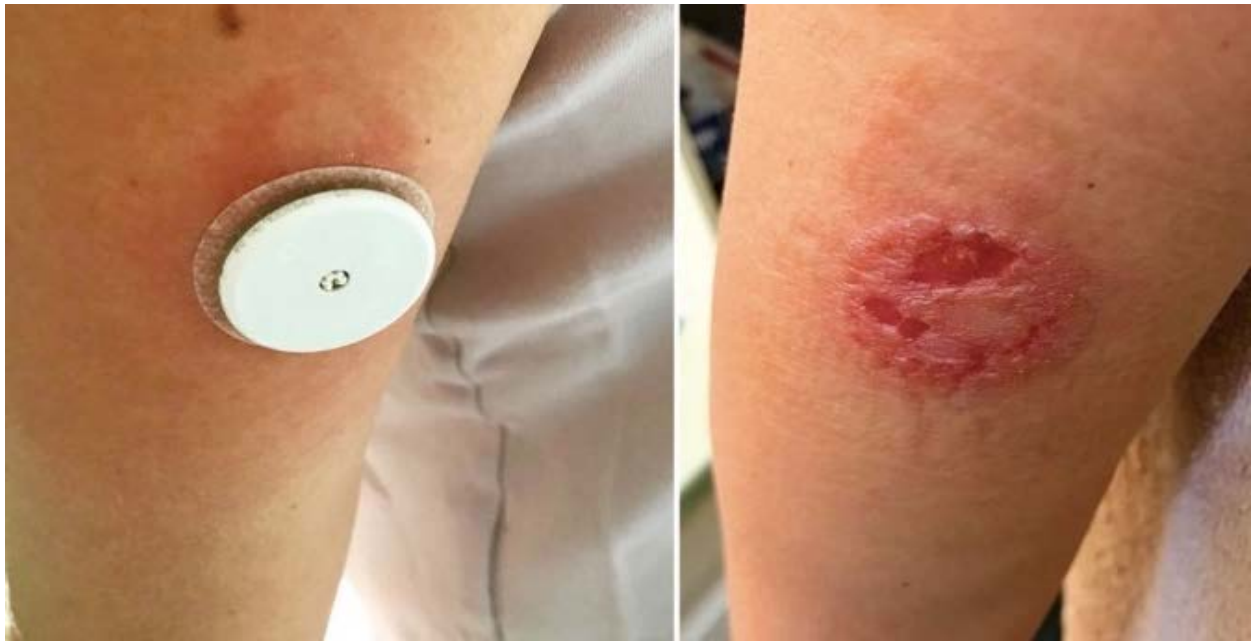
- 3rd Leading cause of death
- 1 in 16 People in the world have been diagnosed
- 1 in 10 People in the US have been diagnosed
- 1 in 3 People in the US currently have diabetes or are pre-diabetic
  - 1 in 2 By 2025
- Nearly $2 Trillion are spent every year addressing diabetes
  - 1 out of every 4 Healthcare dollars address diabetes

The Diabetic’s Dilemma

- 22% of people with diabetes must test blood glucose 4 or more times per day to avoid severe medical issues
- The only test method reliable and accurate enough for all diabetic use cases is the finger prick glucometer
- Finger prick glucometers are painful, inconvenient and require expensive supplies for each use

The Diabetic's Dilemma

- Other available glucometers
  - Frequently cause pain and irritation
  - Measure glucose in skin, not glucose in blood
  - Are not approved for use in all cases
  - **Do Not Replace the Finger Prick Glucometer**
- What is needed is a pain-free, easy to use, blood glucometer
  - An Artemis Device; the **ONLY** finger prick glucometer replacement



Diabetes Complications

- Over long periods of time, regular episodes of high blood glucose concentration known as hyperglycemia lead to diabetic complications that result in:
  - Cardiovascular disease
  - Kidney disease
  - Nerve disease
  - Blindness and amputations
  - Making diabetes and its complications is one of the leading causes of death

Our Solution

Our mission is to enable better management of diabetes with accurate noninvasive measurement of blood glucose concentration.

- No fingersticks
- No blood
- No test strips
- No pain
- No limits on testing

- Exclusivity provided by significant IP protection

Financial Model

	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Hardware Revenue	-	-	4,518,000	300,000,000	360,000,000	664,518,000
Subscription Revenue	-	-	468,520	98,272,240	339,672,240	438,413,000
Total Revenue	**-**	**-**	**4,986,520**	**398,272,240**	**699,672,240**	**1,102,931,000**
COGS	-	-	3,313,200	220,000,000	264,000,000	487,313,200
Gross Margin	**-**	**-**	**1,673,320**	**178,272,240**	**435,672,240**	**615,617,800**
Gross Margin %			**34%**	**45%**	**62%**	**56%**
Headcount & Related	4,000,000	4,800,000	4,800,000	4,800,000	4,800,000	23,200,000
R&D Expense	9,639,375	13,037,625	970,000	910,000	680,000	25,237,000
Operating Expenses	155,532	156,975	439,515	18,907,140	22,657,140	42,316,302
Total Expenses	**13,794,907**	**17,994,600**	**6,209,515**	**24,617,140**	**28,137,140**	**90,753,302**
F&F	115,900	4,800	800	-	-	121,500
Manufacturing Equipmer	-	841,500	3,528,500	3,430,000	-	7,800,000
IT Equipment	148,000	-	-	-	-	148,000
Cap SW	170,000	-	-	-	-	170,000
R&D Equipment	1,085,000	-	-	-	-	1,085,000
Total CAPEX	**1,518,900**	**846,300**	**3,529,300**	**3,430,000**	**-**	**9,324,500**
Total Spend	**15,313,807**	**18,840,900**	**13,052,015**	**248,047,140**	**292,137,140**	**587,391,002**
Net Cash Flow	**(15,313,807)**	**(18,840,900)**	**(8,065,495)**	**150,225,100**	**407,535,100**	**515,539,998**

Business COGS/Pricing Modeling

Artemis NonInvasive SMBGM

- Purchase price: $1200
- Monthly maintenance fee: $68
- Useful life is 36 months
- Return to Artemis is $3648

NOTE: Cost to manufacture $955

Fingerstick SMBGM

- Purchase price: $100
- Monthly disposables: $99
- Useful life is 36 months
- CMS reimbursement is $3664

NOTE: CMS is Centers for Medicare & Medicaid Services

Competing Alternatives

Finger-stick Meters	Continuous Glucose Meters	Noninvasive
Roche Diagnostics	Dexcom	None
Johnson & Johnson	Medtronic	
Abbott Diabetes Care		
Bayer Healthcare		
Boehringer Mannheim		

IP Plan

- We own a key portion of the core technology by virtue of two issued US patents
  - Assigned to our corporation
  - Invented and authored by Artemis founding team
- We also have filed to protect the new design configuration and many variations thereof
  - Primary indication in pursuit is blood glucometry
  - We also have identified many other valuable addressable markets for compact, high-accuracy, portable, non-invasive spectroscopy
- Experienced team on the strategy and execution

Development Gantt (next slide)

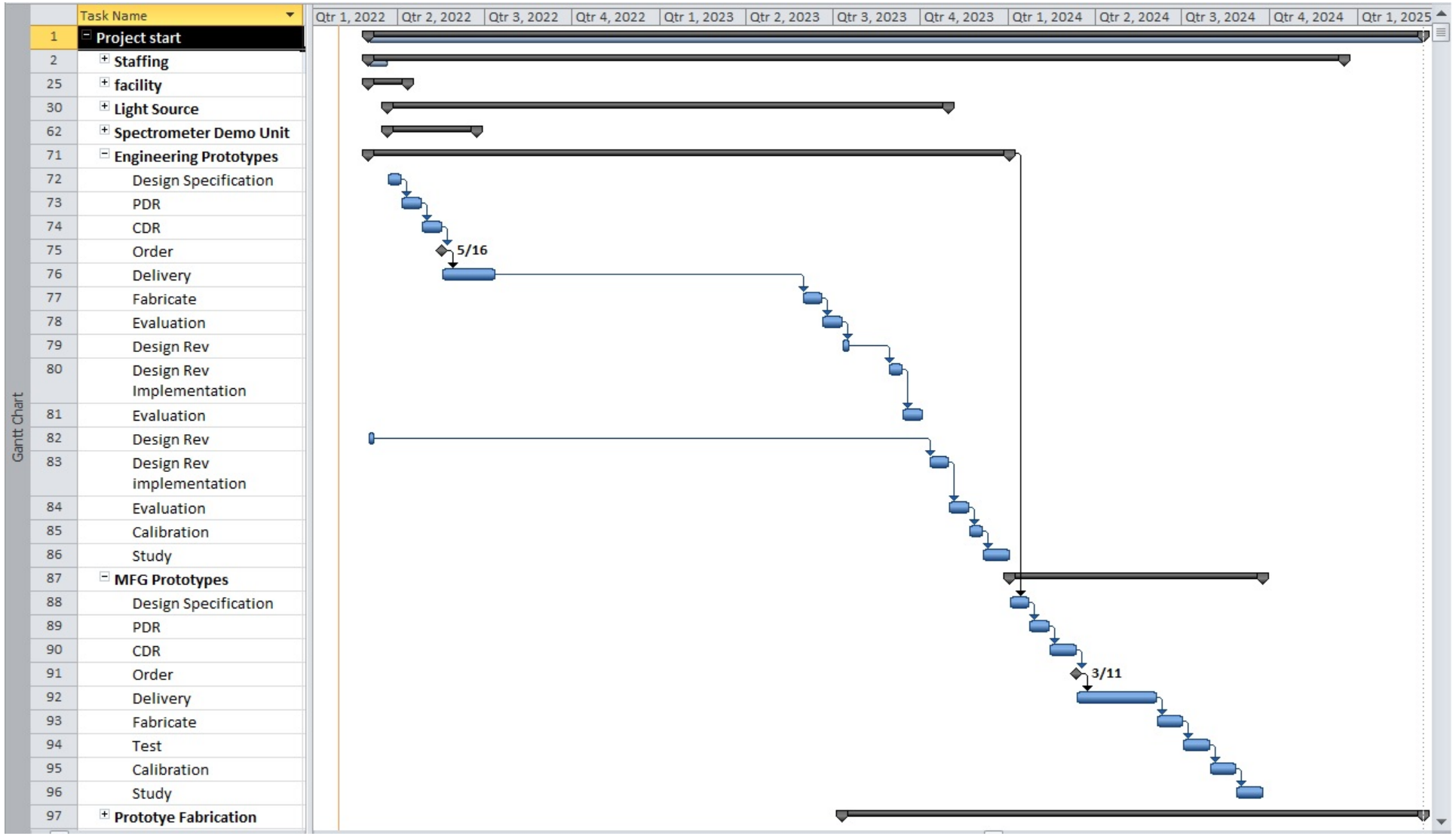
- The US and EU design controls standards are harmonized. Therefore developing a Quality Management System that complies to all is easy and prudent. Also the safety/EMC standards are harmonized for the most part. So testing against one holds for both. Hence the 10 basic steps to get to FDA (and EU) are:

1. Generate Design Requirements and a Development Plan
2. Design and develop the system and hold Design Reviews
3. Build prototypes and test
4. Perform Risk Analysis
5. Conduct design Verification including Safety/EMC testing and Software validation
6. Generate Design Output
7. Develop Manufacturing Processes and Validate
8. Manufacture Units for Clinical Trial
9. Prepare and conduct Design Validation via clinical trial
10. Prepare FDA submission and Technical File for EU submissions

Steps 2 to 5 may have to re-iterate.

Artemis needs a Quality Assurance department along with Engineering to harmonize the quality controlled development process.

Gantt for Key Development



Regulatory US

- There are four basic steps involved in getting FDA marketing clearance in US:
    1. Classify your device and understand applicable regulatory controls.
    2. Select and prepare the correct Premarket Submission.
    3. Send your Premarket Submission to the FDA and interact with the FDA staff during review.
    4. Comply with Applicable Regulatory Controls Including the Establishment Registration and Device Listing

Note that most likely the device will fall under Class II of FDA and will require a 510(k) Premarket Notification submission for marketing clearance.

In step 2, the Premarket Submission must show that the device was developed and tested as follows:

- Design Controls: Class II and class III devices must be designed in accordance with Design Controls under the Quality System Regulation, 21 CFR 820.30.
- Non-clinical Testing: This includes performance verification testing, which is usually conducted by the manufacturer, and compliance verification to Safety and Electro-Magnetic Compatibility standards such as UL 60601-1 and 47 CFR 15b, which is conducted by an accredited laboratory.
- Clinical Evidence: Prior to initiating a clinical study, the study sponsor may need to obtain approval of an Investigational Device Exemption (IDE) by the FDA. The study will also need to be approved by the appropriate Institutional Review Board (IRB). Clinical studies must comply with all applicable IDE regulations and Good Clinical Practices (GCPs).
- Labeling: The labeling for a device must be written according to labeling regulations, 21 CFR 801.

Regulatory EU

1. Classify Your Device and Understand Applicable Regulatory Controls.
2. Prepare a Technical File or Design Dossier for Class III with evidence of compliance to the Medical Devices Directive.
3. Send Technical File to a Notified Body, interact with Notified Body staff during review and Receive a CE Mark certificate from if Class I with Measuring or Sterile function, Class IIa, IIb, or III.
4. Appoint a European Authorized Representative if you have no physical location in Europe and register the medical device with the Competent Authorities, where applicable.

Again most likely the device will fall under Class IIa.

In step 2, the Technical File will require that the device was developed and tested as follows:

- Design Controls: Medical devices must be designed in accordance with Design Controls under a Quality Management System certified to ISO13485.
- Non-clinical Testing: This includes performance verification testing, which is usually conducted by the manufacturer, and compliance verification to Safety and Electro-Magnetic Compatibility standards such as IEC60601-1 and IEC 60601-1-2, which is conducted by an accredited laboratory.
- Clinical Evidence: According to EN540 for clinical investigation.
- Labeling: Labeling is part of Safety standard.

Regulatory Process FDA 510(k)

https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device

https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k

TRADITIONAL 510(k) submission

Most companies must submit a traditional 510(k) Premarket Notification which is a full 510(k) that includes all of the following sections:

1. Medical Device User Fee Cover Sheet
2. CDRH Premarket Review Submission Cover Sheet
3. 510(k) Cover Letter
4. Indications for Use Statement
5. 510(k) Summary or 510(k) Statement
6. Truthful and Accuracy Statement
7. Summary and Certification
8. Financial Certification or Disclosure Statement
9. Declarations of Conformity and Summary Reports
10. Executive Summary
11. Device Description
12. Substantial Equivalence Discussion
13. Proposed Labeling
14. Sterilization and Shelf Life
15. Biocompatibility
16. Software
17. Electromagnetic Compatibility and Electrical Safety
18. Performance Testing ? Bench
19. Performance Testing ? Animal
20. Performance Testing ? Clinical

Regulatory Process FDA PMA

- Applicant submits “informal” PMA Shell to the attention of the CDRH Branch
- Chief of the appropriate review division or to the applications division in the
- appropriate CBER office.
- Applicant submits final PMA Shell to DMC or DCC
- Applicant submits PMA modules in accordance with
- agreed upon schedule (each module subject to a 90-day
- review clock)
- Applicant submits final PMA module, thereby completing
- the Modular PMA (180-day review clock)
- Review division sends a letter to the applicant
- accepting the shell
- Applicant submits user
- fee payment before 1st
- PMA module
- Applicant reaches
- agreement with FDA

Regulatory Process Standards

- EN1441 Medical devices – risk analysis
- EN980 Graphical Symbols for Use in the Labeling of Medical Devices 80/181/EEC
- BS EN1041 Information supplied by the manufacturer with medical devices
- BS EN540 Clinical investigation of medical devices for humans
- IEC601-1-4 Medical electrical equipment - Part 1: General requirements for safety - 4. Collateral standard: Programmable electrical medical systems

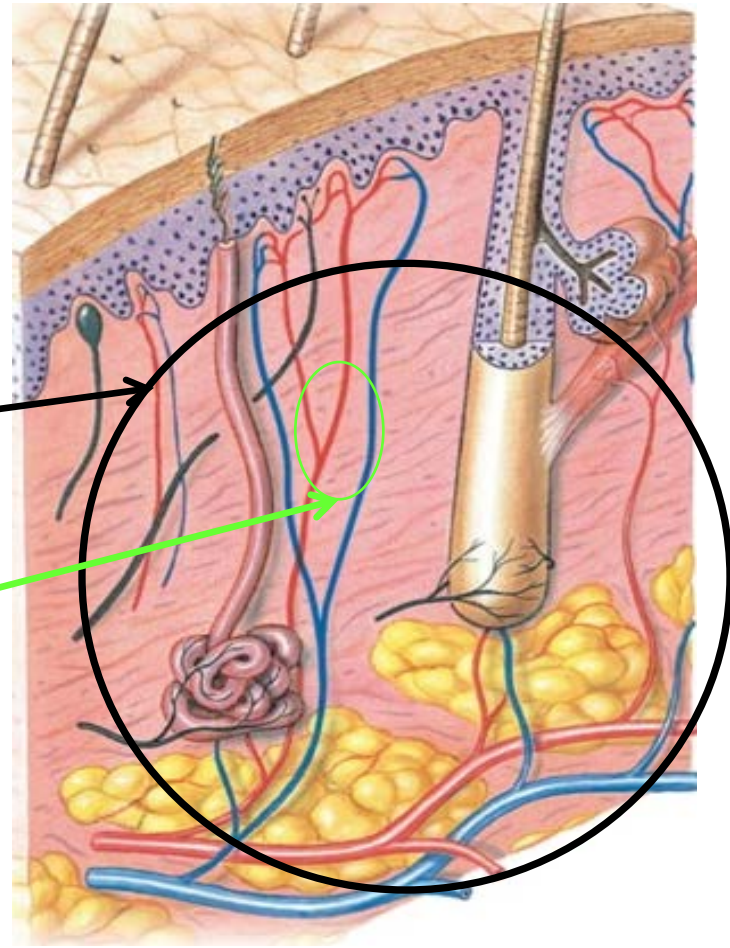
- Any experimentation involving use of a medical device on a human subject falls under the IDE regulation and informed consent. If the medical device is a non-significant risk device, then FDA review of the IDE is not required - all you need is one hospital Institutional Review Board (IRB) to approve your clinical protocol and informed consent form, and you can conduct your study with oversight from the hospital IRB.

Artemis Technology

- The Artemis Device is a Spectrometer
  - A tool that uses the color of a substance to determine how much of the substance is in a mixture
  - We use our eyes to do this every day
  - For example, you can tell if there is a little or a lot of cream in the coffee in the image below, just by looking at the color

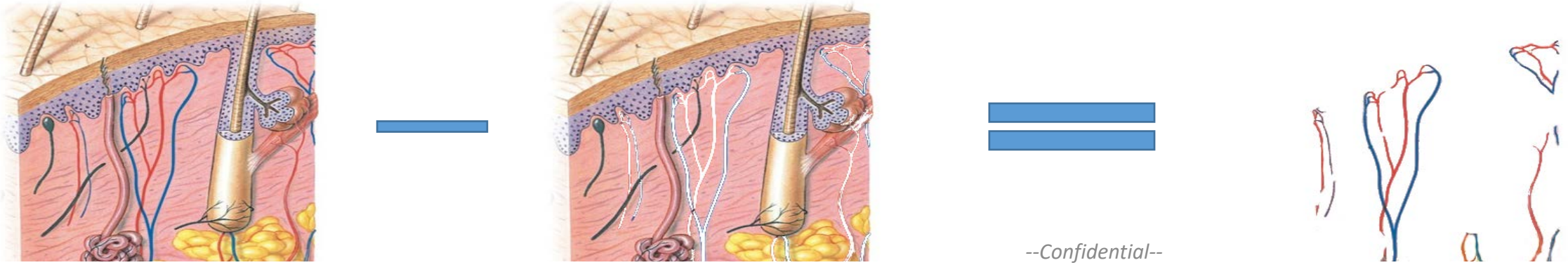
Capillary Blood and Clutter

- To measure blood glucose, the Artemis Device needs to measure the color of the blood
  - Specifically, the **Capillary Blood**
- The skin is cluttered with features other than capillary blood
  - Skin cells and fluid, hair, fat, nerves, sweat glands, etc.
- This is what is measured
- The Artemis Device will isolate this, the capillary



Artemis Unique “LightHunter” Technology Solution

- A single skin measurement is very cluttered.
- But blood changes color during the pulse
  - It is more colored during high blood pressure
  - And clearer during low blood pressure
- The difference between low and high blood pressure measurements is capillary blood only
  - This is called **Pulse Differential Spectroscopy**



Artemis Unique “LightHunter” Technology Solution

- Artemis Pulse Differential Spectroscopy (PDS)
  - **The Artemis Patented approach is what allows the Artemis Device to sample blood glucose and ignore skin**
  - This technique sets Artemis apart from ALL other non-invasive and CGM technologies
  - It allows the Artemis Device to be a ***true*** blood glucose meter

Will It Work?

- We are confident. In 2007, Kanazawa University built an experimental, laboratory sized, Pulse Differential Spectroscopy (PDS) system which was shown to accurately resolve PDS measurements
  - Glucose results were within the FDA statistical accuracy requirements
  - The system was not commercially viable due to the required liquid nitrogen cooling for the ultra-low noise detector
  - It was quite a different configuration because they were trying to address signal-to-noise ratio issues by thermodynamically reducing noise; but it DOES validate where we are headed with this PDS solution