### **RAD**uxtion

INVESTOR PRESENTATION

# RADuxtion

Technology that safely reduces 70%+ of the ionizing radiation exposure for doctors, medical staff, and patients during fluoroscopy procedures

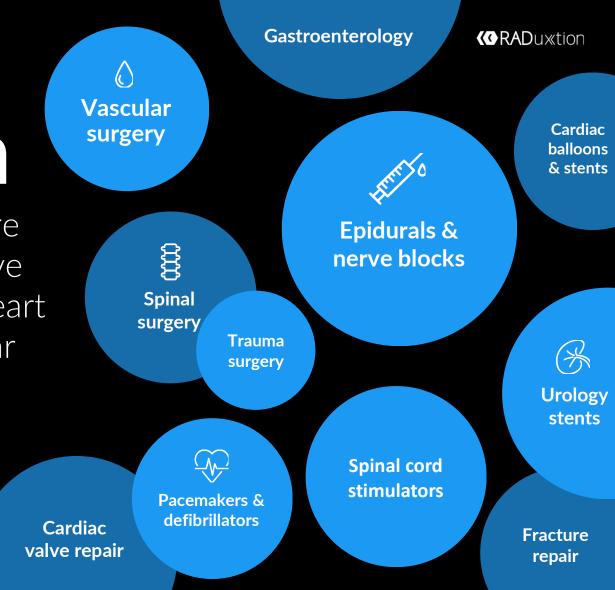


RADuxtion, Proprietary & Confidential.

# 24 million

fluoroscopy procedures are done every year to improve the lives of people with heart disease, peripheral vascular disease, cancer, trauma, chronic pain, etc.

IAEA (International Atomic Energy Agency)





#### PROBLEM

# Doctors and medical staff who perform fluoroscopically guided radiation procedures have a higher risk of cancer and other diseases

Fluoroscopy has allowed major advances in the medical treatment of common diseases, but ionizing radiation is a known carcinogen, and the exposure increases risk of cancer and other diseases.

2X
Brain cancer mortality

2.9x
Breast cancer incidence

Dec. 2024: AMA Delegates Want Better Protection From Ionizing Radiation Exposure

~MedPage Today

Today's methods fall short in meaningfully reducing radiation exposure:

1

Take fewer

images

Use extra shielding

(Lead shields which still leave tissue exposed, "EggNest")

3

Step back from fluoroscope

Cone / Collimate

the image

Use alternative settings



#### SOLUTION

# RADuxtion reduces radiation exposure with predictable and accurate equipment settings

An innovative and patented app with a proprietary algorithm that recommends optimal settings to safely reduce radiation exposure.

- 1. Allows the physician to determine optimal modes and settings to provide best quality images, with the **least radiation needed.**
- Defines modes and settings that will dependably reduce expected radiation production and therefore exposure **before** the image is taken.
- 3. Provides adjustment settings to improve image quality, if needed.



70%-90%

Reduction in total scatter radiation to doctors and staff based on study results

69%-86%

Reduction in total radiation exposure to patients



#### HOW IT WORKS

### Breakthrough technology that optimizes the lowest radiation dose needed

RADuxtion is the first platform that accurately calculates recommended kVp (kilovoltage peak) and mA (milliamperes) settings based on patient-specific data, to reduce the risk of unnecessary radiation exposure.





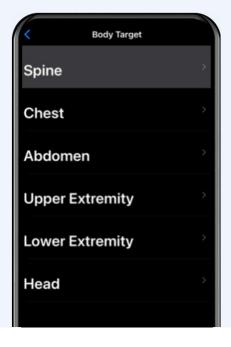


**Body Target** 

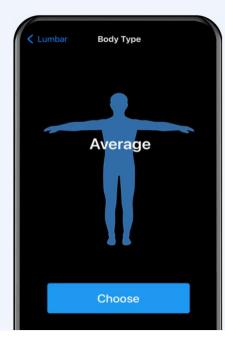


**Body Habitus** 











# Results deliver an 86.7% reduction in radiation exposure for doctors and medical staff based on pilot study

Total radiation exposure with Auto mode settings:

Total radiation exposure with Auto mode settings:

Dose Rate: 43.317 mGy/min Image Duration: 866.1 ms

Total Dose: 621.33 uGy for 1 image

Total radiation exposure with RADuxtion settings applied:

Dose Rate: 16.686 mGy/min Image Duration: 193.6 ms Total Dose: 53.85 uGy for 1 image



#### CASE STUDY

### Validated results based on 150 cases on average per badge reading



Staff has shown no scatter detected on all of their badges for more than 1 year.

- Started at 120-140mRem per 150 cases
- Then with trying to restrict image counts, stepping back, using extra shielding, etc, I got it down to 70-90mRem per 150 cases
- Then I figured out how to achieve the RADuxtion method. With the RADuxtion App, I am now down to 7 to 14mRem per 150 cases





# A \$4B market and an unmet need for reduced exposure to radiation

#### TAM = \$4B

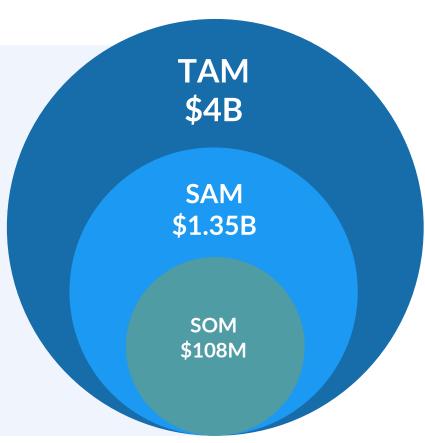
- Over 900K Mobile and Fixed Fluoroscopic devices in use worldwide
- 3-6 physicians use each device
  - Average 4.5 physicians x 900K Fluoroscopic Devices
- 4 million potential licensees

#### SAM = \$1.35B

- Focus on mobile devices sold since 2000.
- 300,000 devices with Average of 4.5 physicians / device
- 1.35M potential licensees

#### **SOM = \$108M**

- At 20% of the 100K US market at 4.5 physicians per device
- \$1,200 annual subscription fee per user (\$.50-\$1 / procedure)
- 90,000 US licensees





### A rapid path for FDA approvals

- 7
- 2<sup>nd</sup> FDA Pre-Submission filed March 2024
- FDA 2<sup>nd</sup> Pre-Sub meeting held May 2024
  - Agreed RADuxtion is "Accessory Device" classified as SaMD (Software as a Medical Device)
  - Does not require de novo review (Reduces complexity and cost of submission)
  - FDA agreed that lab testing can be used to validate efficacy (time and cost savings)
- Next Steps:
  - Final FDA pre-submission and confirm laboratory study design May 2025
  - Working with former FDA statistician to define study design and primary and secondary outcomes
  - After completing FDA Pre-Sub #3, we will proceed with Pivotal Study (1-2 months)
  - Prepare 510(k) submission August 2025: FDA provides review 60 days after submission

Target: Early Q3 for FDA 510k submission, Q3-4 for clearance





### Patents in the U.S. and pending in 9 other countries

#### Patent Family 1:

Operating Parameters +
Deactivating Automatic Exposure
Control ("AEC") to Reduce
Radiation Exposure



1 pending continuation



- 1 active PCT
- 8 Patent Pending with Foreign filings: AU, BR, CA, CN, EP, KR, IN, JP, and MX
- Prosecution has started in BR, CN, EP, and KR

#### Patent Family 2:

Using Equalizing Quotient ("EQ") to Reduce Radiation Exposure

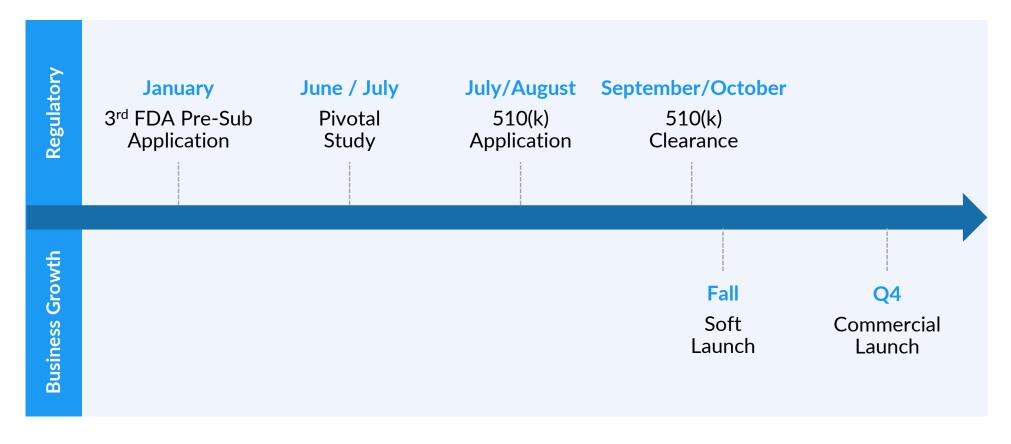


- 1 U.S. Patent: 11,931,196
- 1 pending continuation (recently approved)
- 1 active PCT
- Planned foreign filings: AU, BR, CA, CN, EP, KR, IN, JP,
   & MX





### We'll lead the way in 2025 with breakthrough technology





#### WHY NOW

## The industry is demanding a solution for life-saving technology that doctors and patients will never want to live without

"I do not want to see my colleagues in my clinic with preventable cancers from their preventable exposure to radiation out of their selfless dedication to patient care."

Kristina Novick, MD
On behalf of the American Society of Clinical Oncology

The FDA launched a collaborative Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging, with a focus on fluoroscopy. The goal is to mitigate the factors contributing to the unnecessary radiation.

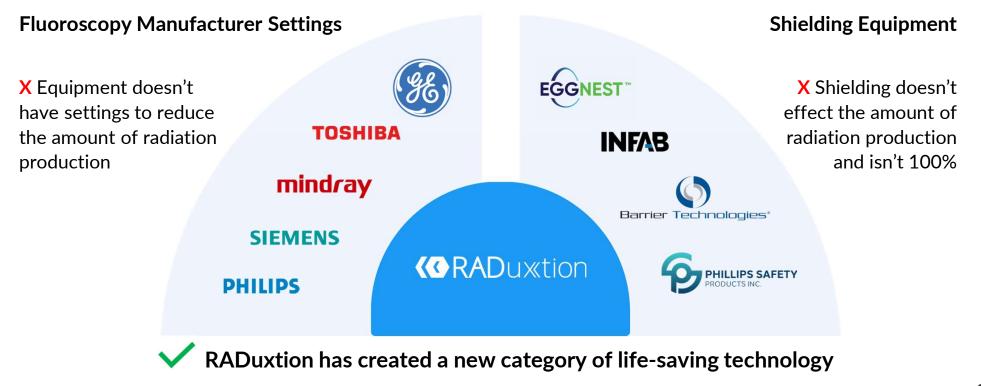
The American College of Radiology (ACR) strongly advocates for significant radiation reduction in fluoroscopy procedures due to its potential for high patient radiation doses, emphasizing the need to optimize imaging techniques to achieve diagnostic quality while minimizing unnecessary exposure.

The "ALARA" principle (As Low As Reasonably Achievable), requires healthcare providers to minimize radiation exposure while still obtaining adequate diagnostic information.



#### COMPETITION

# RADuxtion is the 1<sup>st</sup> technology solution to reduce overall radiation exposure while optimizing image quality





#### **BUSINESS MODEL**

A subscription model that scales easily across our target market with recurring revenue

### \$1,200 / year

- \$100 per license per month
- Custom facility and GPO pricing

#### Licensing:

Manufacturer Licenses







### \$50 million in 5-year sales, with profitable growth

Fiscal Year	2025	2026	2027	2028	2029
Revenues	\$60,750	\$1,345,890	\$5,069,140	\$13,198,130	\$29,329,740
% Growth	na	2115%	277%	160%	122%
Individual Subscription Accounts	300	2,100	6,500	15,700	33,500
Gross Margin	51,638	1,144,007	4,308,769	11,218,411	24,930,279
Gross Margin % of Revenues	85%	85%	85%	85%	85%
Operating Income (EBITDA)	(698,586)	(266,934)	2,486,608	8,670,682	20,992,638
% of Revenues	-1150%	-20%	49%	66%	72%
Net Income	(698,586)	(266,934)	2,106,336	6,503,012	15,744,478
% Growth	na	-62%	-889%	209%	142%
% of Revenues	-1150%	-20%	42%	49%	54%



# Medical and business experts with deep technical expertise to innovate and scale



Dr. Phillip R. Kingma, MD, DABPM, DABFM

Founder & President

- Over 27K interventional procedures performed
- University of Cincinnati College of Medicine



Dr. Michael Blaivas, MD/MBA, FACEP, FAUIM
Chief Medical Officer

- Chief Medical Officer, Echonous
- Chief Medical Officer, ThinkSono
- · Chief Medical Officer, AnavasiDx



Scott Hales, MBA Chief Financial Officer

- Experienced in accounting & financial management, M&A advisory, corporate finance
- Over 45 transactions, >\$1B value



John Wolf, MBA Head of Quality / Regulatory

- MedTech Quality Design Engineer
- Remediation of design history files, FDA compliance audits



**Paul Shin**Regulatory Affairs

- Fmr FDA/CDRH Lead Reviewer
- RA Consultant; J&J Vision, Depuy Synthes, BD



Nelson Patterson, MBA Outside Director / Board Member

- CEO, Anavasi Diagnostics
- Former leader @ P&G, SonoSite, Baxter, Exokinetics, Aerogen, and HealthySole



David Webster, MS
Outside Director / Board Member

- Chief Commercial Officer, Beyond Air
- Fmr CEO, BodyVision Medical
- Fmr COO, Samsung NeuroLogica





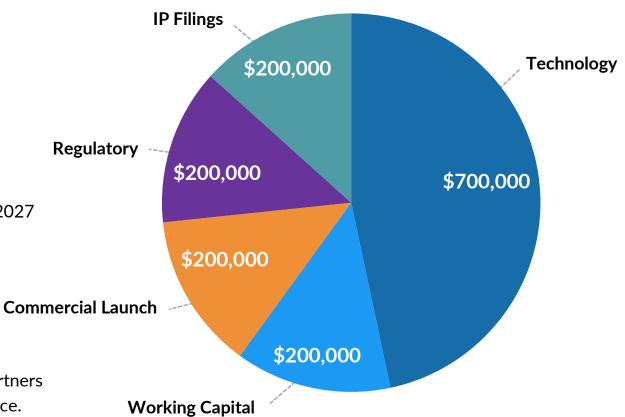
### Opportunity highlights

\$1.5M

#### **SAFE Notes**

- Achieve \$6.5 million in revenue by YE 2027
- Execute on soft launch and commercial launch
- Hire key team members
- Finalize 510(k) submission
- Gather FDA feedback

We are looking for Investors, Strategic Partners and those with a vision to make a difference.





# The Power to reduce radiation... in the palm of your hand.

Dr. Phillip R. Kingma, MD

pkingma@raduxtion.com 317.752.8879 raduxtion.com