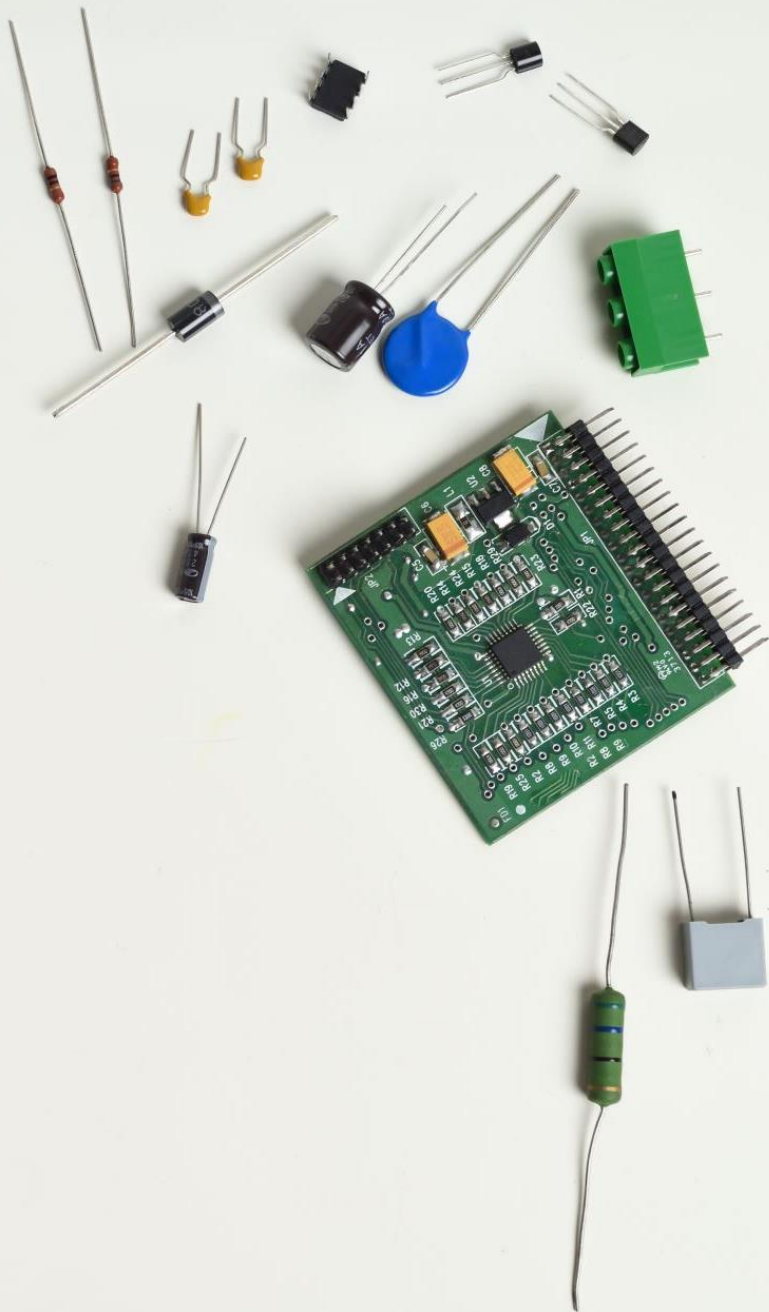




“This little medical device went to market.”

Dr Monika Yazdanian, CEO,  
ToeFX Inc.



## About Monika Yazdanian +ToeFX

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- Joined as CEO of ToeFX in 2019
- I live and work in Hamilton, Ontario
- ToeFX is based at the Venture Incubator at McMaster University in the Life Sciences Building
- Previous roles:
- founding Director of the Forge @ McMaster University
- Director of R&D at the Sargent Lab, Dept. of Electrical Engineering @ U of T
- Founder of e-commerce software platform
- Ph.D., chemical physics, Cornell University
- LL.B. (law), University of Western Ontario



Monika Yazdanian

CEO at ToeFX Inc.

2w • 🌐

...

Milestone day for ToeFX after a VERY busy summer - yesterday we began shipping our ClearToe Serum product for onychomycosis, sold in single-use applicators! It's been a lot of work and I'm very proud of how the ToeFX team has pulled together during the last few uncertain months. #team



ToeFX will be at the Canadian Federation of Podiatric Medicine Annual Meeting in Nov. 2020



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# Clear up toenail fungus

The ClearToe Light Therapy system is designed to clear up toenail fungus in as few as four treatments.





# Let's Play **Go-To-Market** CHALLENGE

**A-Regulatory (i.e., Health Canada)**

**B- Manufacturing standards (i.e., ISO-13485 certificate)**

**C- Device performance standards (i.e., IEC 60601)**

**D- Clinical trial**

**E- Design feedback from Clinical Trial for manufacturing + **packaging** of product**

**F- Supply chain**

**G- IP, or there's nothing to license**

A needs B, C, D and E

D needed C

B needed D, but also A

E needed D

F needed C and E

G needs none but forget at your own risk

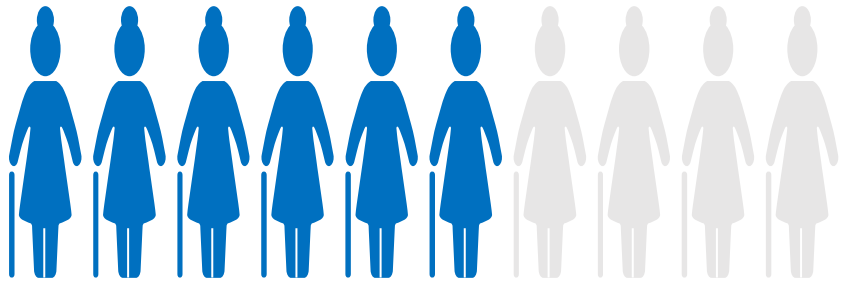


# Millions of people worldwide have toenail fungus.

...it's unsightly, embarrassing and hard to treat.



10-20% of the  
general population



60% of seniors



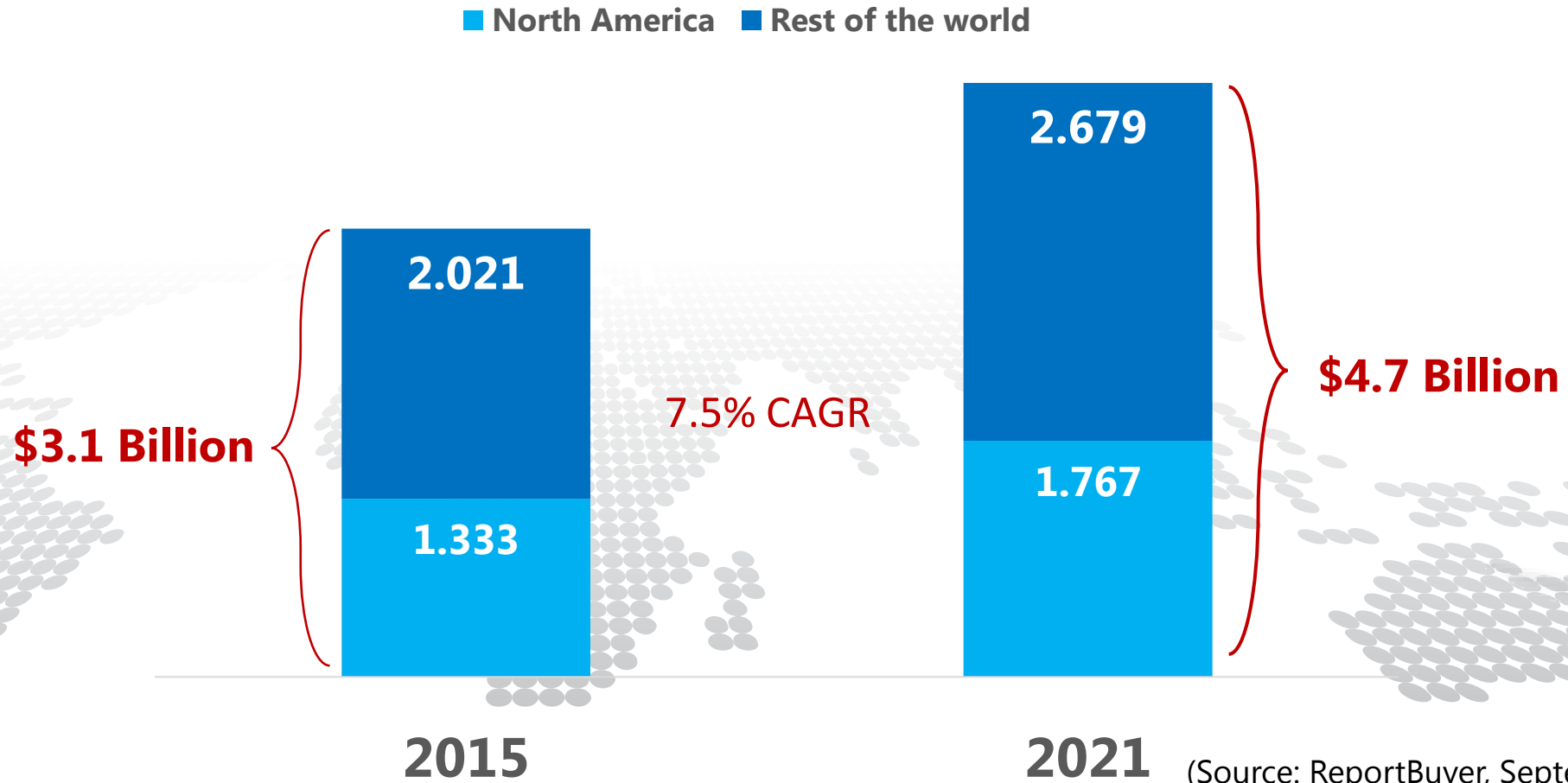
Can have a bad smell,  
sometimes painful

Contagious and can  
migrate to other  
body parts

Embarrassing!

Can lead to  
secondary infections

# Global Toenail Fungus (Dermatophytic Onychomycosis) Therapeutics Market



There is no truly effective treatment for toenail fungus currently on the market.



Hepatotoxicity.



Jublia has a complete cure rate of **only 18%**.



Jublia must be used for at least 12 months.



Post-market warning on lasers.



ToeFX is an end-to-end solution for treatment of toenail fungus.



ToeFX Light Therapy Device



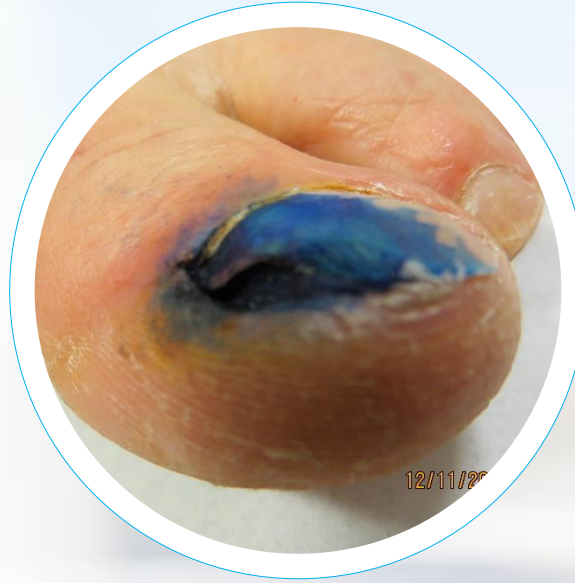
The vision



Competitive advantage: ToeFX clears the appearance of fungal nails within 3-6 months. It is an effective and extremely safe treatment.



Yellow,  
infected  
toenails

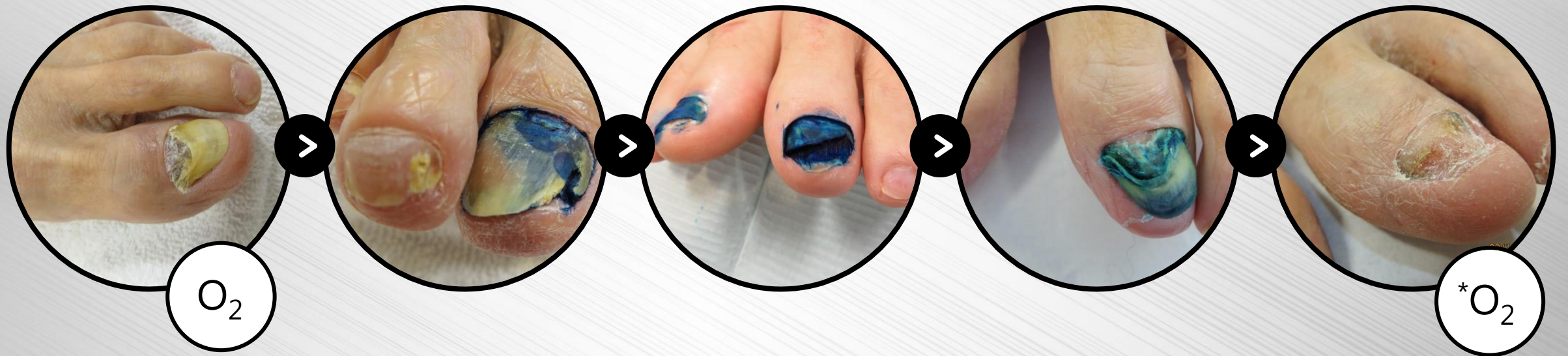


Apply ToeFX  
serum with  
photodynamic  
therapy



Same toe  
after 12  
weeks of  
treatment

# Case Study

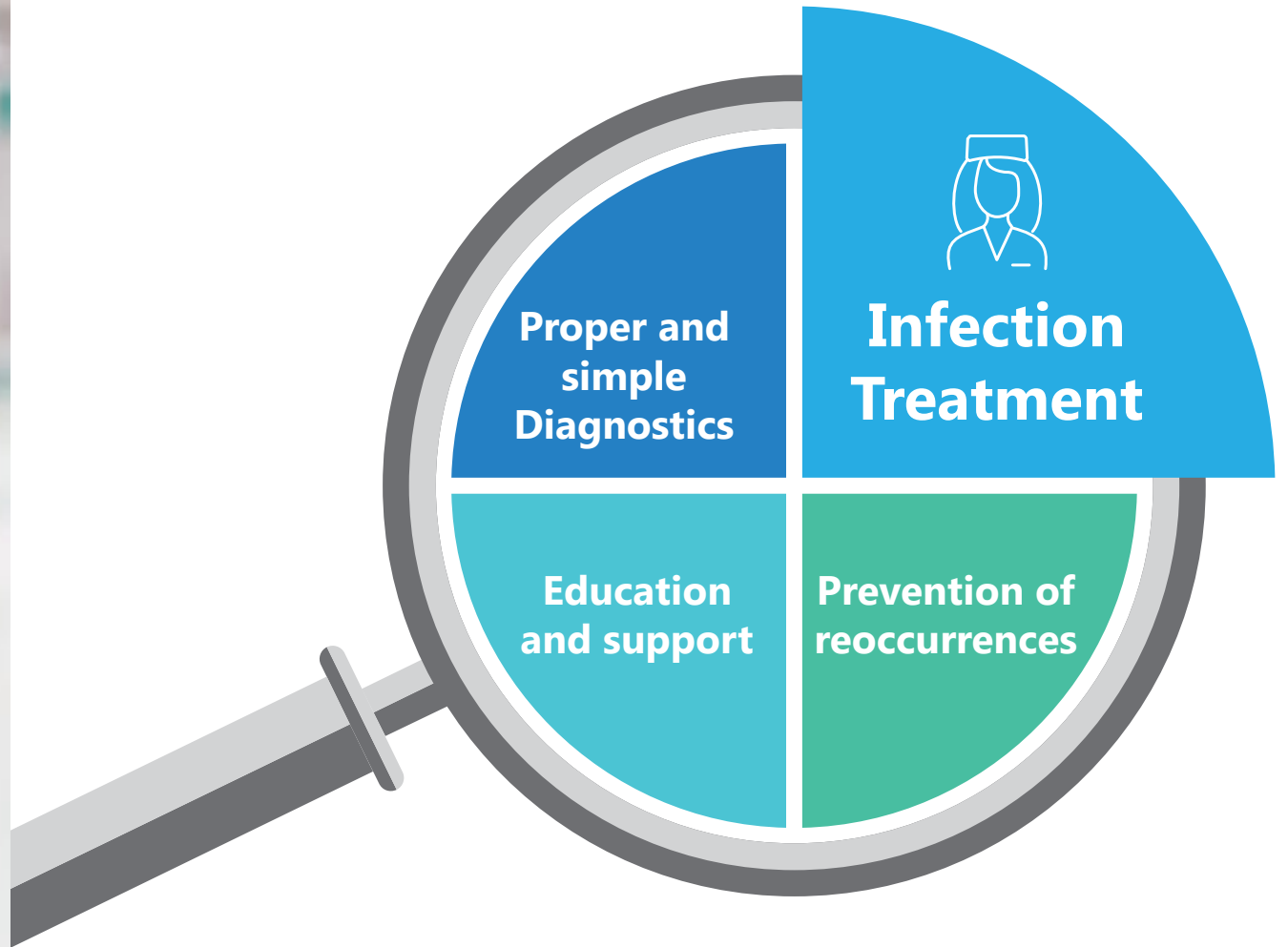




Regulatory pathway

## The Vision

ToeFX is an end-to-end solution for treatment of toenail fungus.







**Dr. Monika Yazdanian, CEO.** Prior to joining ToeFX, Monika Yazdanian was founding Director of The Forge business incubator at McMaster University, Director of R&D at the Sargent photovoltaic lab at the University of Toronto and founder of JL Logistics. Monika has deep experience with early-stage startups and in 2019 was named one of Hamilton's Top 40 under 40. Monika holds a Ph.D. in chemical physics from Cornell University and a law degree from Western University. At ToeFX Monika leads on business strategy and development.



**Dr. Irit Van-Ham, CTO.** Irit Van-Ham holds a Ph.D. in Pharmacology from Tel Aviv University and completed postdoctoral work at the University of Ottawa in Canada. She held senior positions at TEVA Pharmaceuticals and the Ontario Ministry of Health and is an expert in formulation development. Irit is the founder of Olliane Personalized Skin and in 2019 she was shortlisted for CTO of the year at the Toronto "Women in IT Awards". Irit is passionate about the ToeFX product and leads on all aspects of its development.



**Dori Itzhaki, lead engineer.** Dori Itzhaki is a hardware systems engineer. He manages multiple concurrent projects, people and resources from solution definition through design and execution to successful delivery. Dori worked at Intel for several years as a team lead in R&D. Dori manages light source design and development at ToeFX, including specifications, user interface and manufacturing.



**Bernard Lim, advisor.** Bernard Lim founded a medical device company which he grew and led to a highly successful acquisition by a global pharmaceutical. As CEO, Board Chair and Director, he has led the growth of both start-ups and corporate multinationals spanning diverse industry sectors including biotechnology, diagnostics, medical devices, electronics and high technology across US, Canada and Europe. Bernard is a mentor to multiple university spin-out companies and is the resident Health and Life Sciences EIR at Innovation Factory in Hamilton.



**Dana Molckovsky, Medical Science Liaison.** Dana holds a B. Pharm from the University of Toronto and has worked as a Medical Science Liaison and Medical Science Associate at Eli Lilly, AstraZeneca Canada and AstraZeneca Australia. Dana is a pharmacist in Toronto and is a passionate advocate for safe drug consumption. Dana advises ToeFX on sales team development and sales strategies in medical establishments.



**Tammy Lavery, EU and FDA regulatory advisor.** Tammy is the director of RA and QA at Maxtec in Salt Lake City, Utah. Tammy is an experienced director of quality assurance with deep experience in the medical device industry. Tammy's expertise spans medical devices, 21 CFR, Regulatory Requirements, ISO Standards, and U.S. Food and Drug Administration (FDA). Tammy holds a B.S. from the University of Utah.



**Gil Eiges, advisor.** Gil is an internationally experienced senior level executive with a unique background in business, science and technology. Gil has a MSc in Economics from the London School of Economics and specializes in scaling operations. Gil advises ToeFX on business planning, negotiation, execution and general operations.



**Kevin Dai, research assistant.** Kevin Dai is pursuing his B.Sc. in Biomedical Discovery & Commercialization at McMaster University. Kevin supports the ToeFX clinical trial currently ongoing in Hamilton, Ontario.

# We will begin selling in Canada in Q3 2020

Q3 2019

Q4 2019

Q1 2020

Q2 2020

Q3 2020

Q4 2020

Q1 2021

Ex vivo study at McMaster University concluded.

PCT filing

Health Canada Investigational Testing Application approved

IP: PCT initial examination complete

10 prototype lights made and 60 photosensitizer devices

QMS development

Clinical trial begins

MDEL application submitted for Class I photosensitizer device

Pre submission Meeting with FDA

Technical file development for EU

QMS development and ISO-13485 audit + standards

Receive MDEL

IP: Canadian patent #1 issued

Submit *de novo* application to FDA

Clinical trial I ends/trial II begins

MDL approved for Class II medical device

IP: Canadian patent #2/#3 issued. Enter national phase in US + EU

**Start selling to foot clinics in Canada using pharma rep/territory approach**

CE Mark + Technical File Audit (EU)

Clinical trial II ends

**Expansion of sales team**

First sales in EU

Plan for US launch

# Partners

ToeFX is supported by partners across Ontario.



# LaunchYU





# Thank you

[info@toefx.com](mailto:info@toefx.com)

416 933-8637