



September 2024

Examera Progress Report

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1. Executive Summary

Over the past three years, Examera has made significant progress in developing our home-based AI based vaginal discharge diagnosis device. Our team, comprising two physicians and one , one obstetrics & one Psychologist . We have secured a patent in Canada, hired an accountant, rented an office, and engaged in extensive networking and marketing activities. Despite facing immigration challenges and family-related concerns, we have achieved remarkable progress including: patent registration, device development and networking.

2. Company Overview

Company Name: Examera Technology Inc.

Founded: 2021

Founders:

- **Arta Ariapad** as COO (Physician Specialist)
- **Arezoo Hesamifard** as CMO(Physician Specialist)
- **Zahra Rabani** as CEO(Psychologist)
- **Mahshid Fooladi** as Director of Product Management (Obstetrics)

Mission Statement: To provide effective and convenient home-based diagnostic solutions for individuals with microbial Vaginosis.

3. Key Milestones

3.1 Patent Application

The earliest and the most significant milestone was applying for registration and securing a patent in Canada for our innovative device. This patent protects our technology and positions us strongly in the market. (March 2021)

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3.2 Regulatory Meetings

We have attended numerous meetings with regulatory experts to understand the classification of our device and the data collection process required by Health Canada. This has been crucial for our progress toward regulatory approval. (Started in September 2020 to present)

3.3 PR

successfully Examera approved by IRCC on December 2023 .

3.4 Office and Accountant

To streamline our operations, we rented an office and hired an accountant to manage our tax and payroll expenses.

3.5 Networking and Marketing

Our team has actively engaged in networking and marketing activities, attending industry exhibitions and startup events, and connecting with potential clients and investors. (Started in 2021-present)

4. Regulatory Compliance

4.1 Health Canada Certification

Securing Health Canada certification has been one of our primary goals. The certification process has been challenging due to our prototype manufacturer's lack of required certification. This has necessitated additional time and effort to ensure compliance. (Started negotiation with PHL distributions company in May 2024 till now)

4.2 Data Collection for regulatory submission

Collecting sufficient treatment data has been critical for our regulatory submissions. Arta Ariapad, after going back to Iran, has been working with trusted clients to gather this data, which has informed our device enhancements and supported our Health Canada application. (Started in October 2020 till now)

5. Device Development

5.1 Prototype Development

Arta Ariapad has worked closely with the manufacturer to address technical issues identified during the treatment of sample clients and reinforce the device using calibrator. These efforts have been essential in refining our device to ensure it is safe, effective, and user-friendly. (Received first one in July 2021 and Started the second one from March 2022 till now)

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5.2 Additional Features

We are continuously working to enhance our device's capabilities, particularly for addressing Chlamydia vaginosis. Arezoo Hesami & Mahshid Fooladi conducted the research for the idea of addressing diagnosis with Examera. There are some negotiation documents in this case with KF forum. The data collection started from August 2022 till now.

6. Networking and Marketing

6.1 Marketing Materials

We have developed marketing materials, including business cards, brochures (By Arta Ariapad) and Pitch Deck (By Ms. Rabbani and Ms. Fooladi), to support our networking and marketing efforts.

6.2 Industry Exhibitions

Ms. Rabbani has attended various industry exhibitions, such as Iranian Research Organization for Science & Technology, to network with professionals, explore potential partnerships, and stay updated on industry trends. Her research efforts have also contributed to improving our device.

6.3 Professional Associations

Arta Ariapad has engaged with Gynecology & Obstetrics associations and other experts in Iran, expanding our network and gathering insights that inform our development process.

6.4 Startup Events and Competitions

Arta & Mahshid has focused on presenting our device at startup Canada events such as KF forum events, pitching to potential clients and investors, and building relationships with expert medical device registration consultant companies to streamline our Health Canada application process. (May 2022-May 2024)

Ms. Hesami participated in One Idea one world online competition in Turkey and won the prize. (Feb. 2021)

Arta & Mahshid participated in webinar interacting with FDA and Regulatory bodies in Jan 19 2023

6.4 Networking Development

Communicate with experts, investors, medical device companies, dermatologists and regulatory specialists in person or online through email and social media.



7. Financial Management

7.1 Accountant and Payroll

We hired an accountant to manage our tax and payroll expenses, ensuring financial stability and compliance. (August 2022 till now)

7.2 Office Rental

Renting an office has provided us with a dedicated space for operations, contributing to our productivity and efficiency. Agreements are attached.

7.3 Budget Allocation

Our financial resources have been allocated to research and development, regulatory compliance, marketing, and operational expenses. We have carefully managed our budget to ensure sustainable growth.

8. Challenges and Solutions

8.1 Regulatory Delays

Challenge: Delays in the Health Canada certification process due to the prototype manufacturer's lack of certification.

Solution: Mahshid Fooladi has been working diligently with the manufacturer to address these certification issues, ensuring compliance with regulatory standards.

8.2 Data Collection

Challenge: Collecting sufficient treatment data to validate additional options for the device.

Solution: Arta Ariapad return to Iran and work with trusted clients have provided the necessary data to support our device enhancements/development and regulatory submissions.

8.3 Immigration and Family Concerns

Challenge: Immigration challenges and family-related concerns for team members working in Canada. delay in Arta Ariapad PR application process according to comprehensive security screening

Solution: Despite these difficulties, our team has shown resilience and adaptability, continuing to make significant progress in our project.



9. Future Plans

9.1 Health Canada Approval

Our primary goal is to secure Health Canada approval for our device, ensuring it meets all regulatory requirements for safe and effective use by Canadian clients. (April 2025)

9.2 Market Launch

Upon receiving regulatory approval, we plan to launch our device through direct-to-consumer sales, medical distributors, and partnerships with healthcare providers. (June 2025)

9.3 Product Expansion

We aim to expand our device's capabilities to include additional diagnostic options for other microbial vaginosis, positioning Examera as a comprehensive home-based solution.

9.4 Increased Market Penetration

We will continue our networking and marketing efforts to increase market penetration, aiming to capture 5% of the North American Diagnostic vaginal discharge diagnostic device market.

10. Angel Investors and Funding

10.1 Angel Investors Meeting

After getting the Letter of Support from Keiretsu Forum, our team attended a series of angel investor meetings to secure additional funding for our startup. These meetings were crucial for building relationships with potential investors and gaining financial support to further our development and regulatory efforts.

10.2 Escrow Account

Following the investor meetings, we deposited the required amount into an escrow account for our business. This step was essential for ensuring that the funds are securely managed and utilized for the intended purposes, including product development, regulatory compliance, and market expansion. (Oct. 2023)

10.3 Funding Utilization

The funds secured from angel investors will be allocated as follows:(July 2024)

- **Research and Development:** Enhancing the device's features and functionality.
- **Regulatory Compliance:** Covering the costs associated with Health Canada certification and related regulatory processes.
- **Marketing and Sales:** Expanding our market reach and promoting the Examera device to potential clients and partners.

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- **Operational Costs:** Ensuring smooth business operations, including payroll, office expenses, and other administrative costs.
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11. Market Surveys and Data Collection

11.1 Initial Surveys

To gain insights into the market needs and preferences, we initially conducted surveys on our website and social media platforms. The feedback collected provided valuable information about user expectations, preferred features, and potential improvements for our device. (Jul. 2022)

11.2 Extended Surveys

Recognizing the diverse population in Canada, we are going to extend our survey efforts to collect data from different communities including Family doctors, gynecologists, and obstetrics Canadian Medical Association (CMA) ,Canadian Foundation for Women's Health,The Society of Obstetricians and Gynecologists of Canada (SOGC). (started June2023 till October 2024)

11.3 Survey Implementation

Our extended survey includes questions about:

- **Patients conditions:** Prevalence and treatment preferences.
- **Cultural considerations:** Specific needs related to cultural practices and beliefs.
- **Pricing Strategy:** Determine an optimal price point based on customers' willingness to pay

11.4 Data Analysis

The collected survey data is being analyzed to identify trends, preferences, and potential areas for improvement. This analysis informs our product development and marketing strategies; ensuring that Examera meets the needs of a diverse customer base.

11.5 Community Engagement and networking

Engaging with various communities through surveys also helps build relationships and trust. By understanding and addressing their specific needs, we aim to create a more inclusive and effective product.

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12. Conclusion

Despite the challenges faced over the past two years, Examera has made significant strides in developing our home-based AI-based diagnostic device. Our team's dedication, strategic networking, and problem-solving capabilities have positioned us well for future success. With the support of angel investors and the funds secured, we are confident in our ability to bring Examera to market and achieve our business goals. We remain committed to providing an effective, convenient, and affordable solution for individuals suffering from all kinds of microbial vaginosis.

By continuing our focused efforts on regulatory approval, product development, and strategic networking, we are confident in our ability to bring Examera to market and achieve our business goals.

Appendices

Appendix 1: Patent Application Details

- Overview of our patent application process and status in Canada.

Appendix 2: Meeting Reports

- Detailed

Appendix 3: contract and agreement

- Accountant contract and office rental agreement

Appendix 4: Payments

- Detailed payroll payments, rents