

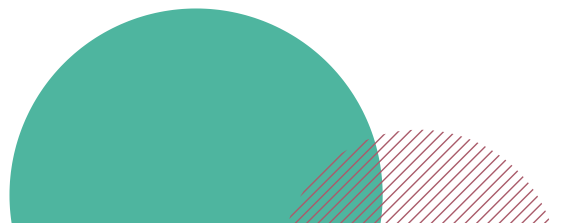
EXAMERA STARTUP REPORT

MARKETING & BUSINESS TEAM

January 2021



Examera
HER HEALTH IN HER HANDS



EXECUTIVE SUMMARY

Our Mission

Examera offers an innovative and user-friendly solution to tackle some of the most common women health issues. We envision Examera to become the name brand for women's health and become a platform for women to control their health and receive health-related products.

Our Product

Examera is a state-of-the-art and easy-to-use device for vaginal health monitoring. It provides gynecologists with relevant parameters such as pH, color, and odor, essential for accurate vaginal infection diagnosis. With Examera, patients can eliminate the need for unnecessary doctor visits while still being able to monitor their vaginal health regularly.

Our Competitive Advantages

Key competitors in the vaginal health self-diagnosis test market are BD MAX, Natureland, Youcount, and VS-Sense. While

BD MAX is restricted to clinic use and other competitors only measure one parameter, Examera is able to stay above the competition with its integrated technologies that make it an accurate, reliable, user-friendly, and affordable solution.

Our Market

The total addressable market in North America for Examera is worth \$11 billion. Examera aims to target 5% of this market, making up a total of \$15 million as the obtainable market. To generate revenue, Examera device and accessories will be sold to general practitioners, gynecologists, obstetrics, and clinics. The device is priced at \$749. Other disposable components such as probes and plates will be offered at \$8 and \$1 each, respectively. Examera also comes with a monthly software subscription for all device users at \$19.99. In the long term, Examera aims to reduce its production cost and expand to the general public health market.





Our Marketing Strategy

Marketing the product in North America, Examera first needs to obtain Class II medical device approval from Health Canada and the FDA. It will then partner with gynecologist and medical device distributors to sell the product. Other strategies such as cause marketing, social media advertisement, informative marketing will be implemented to raise brand awareness. Examera aims to capture 15% of market share by year 5.

Challenges and Exit Strategies

Being the new entrant, Examera will face some challenges such as limited consumer awareness, high competition, high product prices and high initial capital associated with acquiring regulatory approvals. These barriers can be alleviated with Examera's comprehensive business model and innovative products. Several risks involved with the business have been identified, namely changes in medical regulations, device malfunction and misdiagnosis, data breach, competition threats, and brand-reputation damage. The following report points out some measures to take to mitigate and prevent these risks. Ideal exit options for Examera are company acquisition, management buyout, IP licensing, and IPO.



Financial Considerations

It is projected for Examera to sell \$490,849 for the first year. This amount will grow steadily to reach \$3,604,792 by the end of the fifth year. The company is required to sell at least 1005 units in order to reach its break-even-point. Examera starts making \$111,392 profit in the third year, which reaches \$1,162,502 by the end of the fifth year. This will create an average gross profit margin of 66% during the first five years. For the first year, Examera initiates the operation with six employees, including its four founders, with an average salary of \$60,000 per staff. The number of employees is projected to double by the end of the fifth year.

Start-up Financing Requirement

The founders will bring in \$200,000 to cover the startup costs for the first year. In addition, Examera seeks to raise \$75,000 and \$30,000 through Angel investment and the Canadian Scientific Research and Experimental Development (SRED), respectively

BUSINESS CONCEPT

Examera is a state-of-the-art technology that helps gynecologists monitor their patients' vaginal health with accurate, easy-to-use, and inexpensive device assisted by IoT, ANN, and AI. Examera enables rapid vaginal infection diagnosis by simultaneous measurement of relevant and crucial parameters such as pH, color, and odor. The system can detect various vaginal diseases such as Gardnerella (BV) and Candida (Fungal Infection).



POTENTIAL CUSTOMERS AND BENEFICIARIES

Examera will enter the Canadian market through medical device distributors and direct outreach to the general practitioners, gynecologists, obstetrics, and gynecology clinics in Ontario, targeting women's health. Examera will then expand its business to other provinces in Canada and general women's health market.

4000

gynecologists in Canada¹

92,000

physicians in Canada¹

5,000,000

cases who can benefit from
Examera in Canada

48,000,000

cases who can benefit from Examera
in the U.S

These physicians and clinics are the main source of revenue generation for Examera. Subsequently, Examera will be generating revenue from the general public section by selling directly to patients who self-monitor their key measurements' levels to maintain their vaginal health. In addition, doctors can use Examera's application to carefully monitor the patients' state of health. This will be done through Examera's preparatory software, which has a fixed monthly subscription fee.

The followings are the potential customers and beneficiaries of Examera:

- Family doctors, gynecologists, and obstetrics
- Canadian Medical Association (CMA)
- Canadian Foundation for Women's Health
- The Society of Obstetricians and Gynaecologists of Canada (SOGC)



PROBLEM

Vaginal diseases are some of the most common reasons women go to the doctor. These problems are usually accompanied by symptoms such as itching, burning, pain, abnormal bleeding, discharge, etc. One common vaginal disease is vaginitis, and inflammation of the vagina that can occur due to bacterial or yeast infection. Bacterial vaginosis (BV) is a common type of vaginitis caused by the overgrowth of natural bacteria in the vagina, which upsets the natural balance². In order to shed light on the significance of the early detection of vaginal disease, some key facts have been presented below:

- 40% of women with vaginitis leave an initial medical visit undiagnosed³
- Up to 75% of women experience at least one case of VVC, TV, BV in their lifetime³
- 40% - 45% will have 2 or 3 of this vaginal diseases³
- These infections result in approximately 10 million office visit per year³⁻⁷
- Most women found to have BV (84%) have reported no symptoms^{3,8}
- Early diagnosis can lead to milder treatment, which is usually missed and costs more for the government of Canada to treat³
- Multiple components increase test labor intensity and marginal cost
- Lack of electronic data capturing by existing solutions leads to no medical history for patients
- Existing at-home solutions measure only one parameter such as pH, which is not accurate enough for the proper detection of vaginal disease

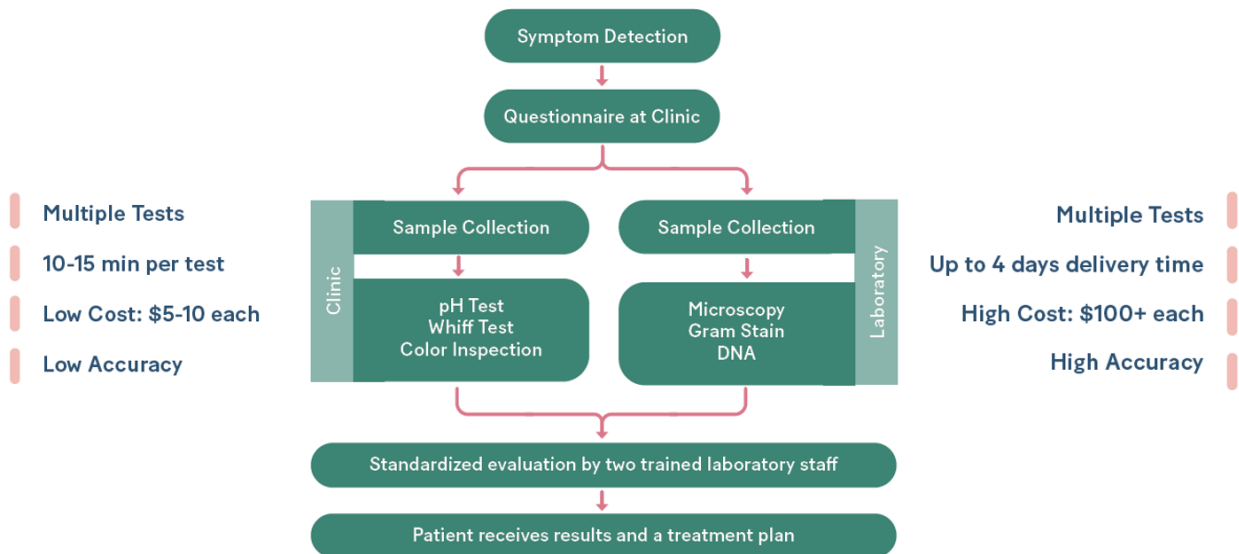
The early detection and diagnosis of vaginal problems are crucial in treating these issues. Examera offers a rapid and easy-to-use solution to screen bacterial vaginitis as well as other vaginal disease and provides early detection capability.

SOLUTION



Examera is a technology that aids women in monitoring their vaginal health with accurate, easy-to-use, and inexpensive device assisted by IoT, ANN, and AI. Using Examera, healthcare providers can receive timely updates on a patients' test results for remote monitoring. Thus, the workload will be whittled down to in-practice testing. Women can regularly self-monitor their key measurements' levels to maintain their vaginal health and build a personal medical history database. Additionally, they can record and compare these results and data with normal industry benchmarks and to carefully monitor their state of health while providing valuable information for the improvement of women health science.

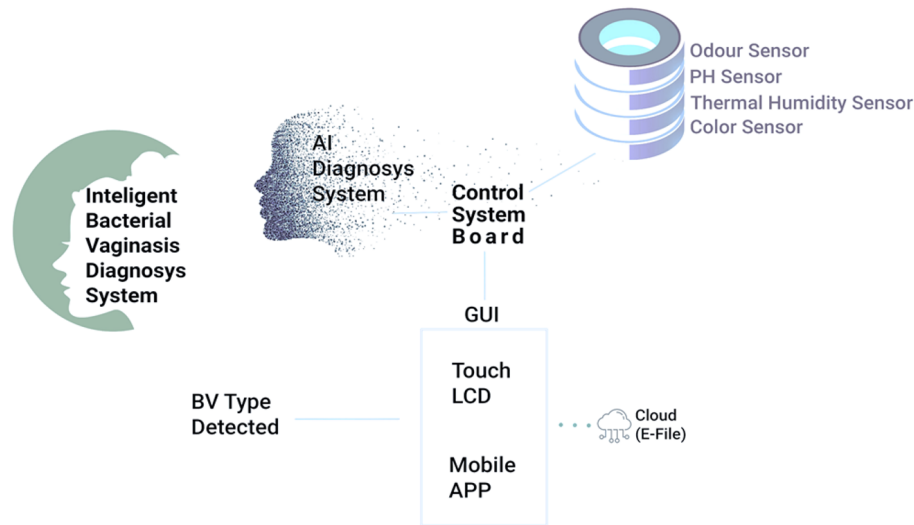
Current diagnosis process:



Currently, the test for diagnosis of vaginal disease is done by collecting vaginal discharge samples in clinics and measuring its pH, odor, and colour in clinics or through microscopy, gram stain, and DNA test in laboratories. These methods are suffering from low accuracy, long diagnosis time, or high costs. Examera is able to produce accurate results in a short time and with low costs eliminating the need for patients to have regular and unnecessary doctor visits.

TECHNOLOGY AND INNOVATION

Examera offers hardware and software solutions to health providers and women to rapidly get tested for various vaginal diseases, specifically with a focus on bacterial vaginosis (BV). The hardware device measures the collected sample's color, pH, and odor. Additionally, it can determine the presence of Gardnerella Vaginalis (BV) and Candida (Yeast Infection) with a high level of accuracy.



Examera Hardware

Examera hardware incorporates multiple sensors that increase the efficacy of the diagnosis. The three main criteria for vaginal infection diagnosis, pH, the color of discharge, and odor are all measured with the Examera hardware device. After the sample is collected with a swab, it is placed in the sample holder. The device probes measure multiple variables, which are directly communicated with the software for diagnosis. In addition to the discharge's physicochemical properties, the device also measures the biological activity in the discharge by providing information about the presence of bacteria or fungi.

AI-Based Software Solution

Upon registering with the Examera software, the physician will connect the device to the software through which the results will be analyzed. The AI-powered diagnosis platform will provide the diagnosis and will recommend treatment options to the physician. The patient will be able to separately connect their device to their profile, which will send updates to the physician. This feature will enable the tele women-health aspect of the Examera platform and reduces the need for an in-person visit.

INNOVATION OVERVIEW

The followings are the innovative ideas incorporated in Examera:



High efficiency

Examera provides healthcare providers with a seamless, uninterrupted, and user-friendly testing device that can quickly perform the test at a fraction of the cost of existing solutions.



Innovative business model

General practitioners, obstetrics, gynecologists, and other healthcare professionals are the channel partners introducing our device to patients. They can receive back-office support, and patients will be directly in control of their healthcare data.



One-stop solution

for accurate vaginal infection diagnosis. Due to each test's limitations, physicians need to run multiple tests to distinguish between various vaginal infections. Examera provides multiple measurements through one sample and a software suite that analyzes the patient result and recommends management plans to increase care quality.








AI-based software

Examera currently has access to over 300 test results to train various recommendation engines to support healthcare professionals' diagnostic and treatments

COMPETITIVE ADVANTAGES

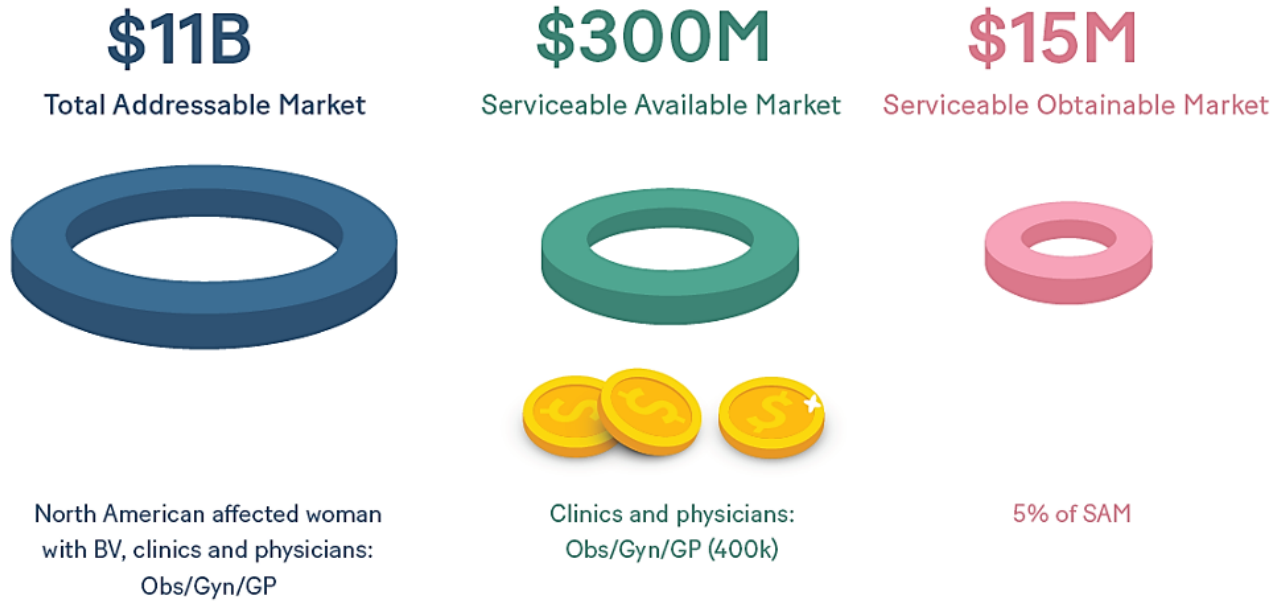
The competitive analysis table illustrates Examera’s features in comparison to its key competitors. As demonstrated, Examera stays above the competition with its integrated technology, versatility, affordability, and test speed.

		Features							
		pH Test	Odor Test	Color Test	BVClue	AI-based Diagnosis	Test Time	Usage	Test Method
Products	Examera 	Yes	Yes	Yes	No	Yes	30 Seconds	Home, Clinic	Vaginal Discharge
	Youcount 	Yes	No	No	No	Yes	2 Minutes	Home, Clinic	Urine
	BD MAX 	Yes	Yes	No	Yes	No	3 Hours	Clinic	Vaginal Discharge
	Natureland 	Yes	No	No	No	No	20 Seconds	Home	Vaginal Discharge
	VS-SENSE 	Yes	No	No	No	No	10 Seconds	Home	Vaginal Discharge

As demonstrated above, Examera outperforms its competitors in all fields thanks to its sophisticated yet affordable state-of-the-art technologies. For example, Examera is the only device (except BD MAX) among its competitors with integrated pH, odor, and color tests for both home and clinic usage to produce the most accurate results while keeping its price lower than similar products. Examera’s competitive advantage over BD MAX is its affordability and faster test results using AI, which makes it suitable for both clinics and home users while BD MAX only targets the clinics.

MARKET

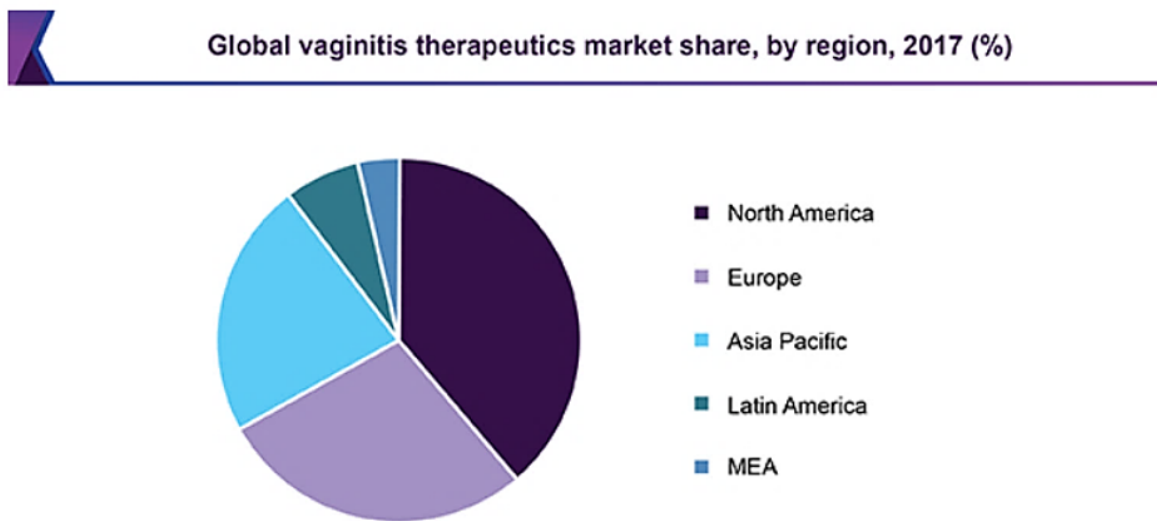
The total addressable market for Examera is estimated to worth \$11 billion (including North American women affected with BV, clinics, gynecologists and general practitioners). From this potential market, \$300 million is the serviceable available market (SAM), consisting of clinics, gynecologists and general practitioners (GP).



Assuming we can target only 5% of this potential market, the serviceable obtainable market (SOM) is worth \$15 million. It is also estimated that the market growth for this industry in North America is 2.4%, which demonstrates the growth potential of this lucrative business.

GLOBAL MARKET

The global vaginitis therapeutic market is anticipated to expand at a CAGR of 8.4% (2.4% in North America) during the forecast period (2014-2025). North America leads the global market owning more than a third of market share. Established healthcare infrastructure in North America along with the high prevalence of disease and the presence of key manufacturers are the major factors responsible for such a large market share. Favorable government initiatives and growing target population are also among the factors that propel market growth⁹.



It is predicted for the Asia Pacific to witness the fastest growth with a CAGR of around 9.6% during the forecast period (2014-2025). This rapid growth is associated with high unmet clinical needs, rising disposable income, increased awareness about early diagnosis, and availability of effective drugs in emerging countries, such as India and China⁹.

BUSINESS MODEL

To generate revenue, Examera can be sold directly to clinics for doctors to lend or rent out to patients or run tests on their facilities. They can receive timely updates on the patient's test results for remote monitoring. So, the workload will be cut down on in-practice testing. Each device is planned to be sold for \$749 to the clinics, GPs, and gynecologists; while it costs \$240 to be manufactured. This will create a 70% gross profit margin. Additionally, some accessories are disposable and will be supplied by manufacturer, such as probes (\$8 each) and plates (\$1 each), which cost \$2.5 and \$0.1 each to manufacture.

Examera software solution will provide a secure text messaging service that can be used to answer patients' questions, allow patients to update their condition, and to remind patients to adhere to their treatment or to transfer referrals to specialized healthcare providers. The software's subscription fee is \$19.99 monthly, which can be accessible to all patients, clinics or doctors that use Examera device.

Long-Term Features

In the long term, Examera will reduce its production cost and will enter public health market. Women can get connected to registered nurses quickly, share their screening and get professional supports. The platform will allow quick and low-cost visits to gynecologists to further assist with the accessibility of these professionals in various communities. Ultimately, we envision Examera to become the name brand for women's health and become a platform for women to control their health and receive health-related products.

MARKETING STRATEGY

Examera will implement a go-to-market strategy through the following channels:



Get Class II approval

from Health Canada, and file 510K with the FDA to get approval to be able to sell the product in North America.



Partner with a gynecologist

to collect clinical data for sales case studies.



Approach medical device distributors

and head positioning system providers to sell products in North America.



Digital marketing

Social media marketing, SEO, Search Engine Marketing (SEM), etc.

Examera will have a strong online presence for the purposes of customer acquisition, raising awareness around the diseases, raising brand awareness, and sales.



Cause marketing

Raising awareness around women's vaginal diseases. The company will inform women of related diseases, which will lead to increased sales indirectly.



Print advertisement

Health magazines and women's magazines, such as Women's Health Magazine, Canadian Woman Magazine, etc. Examera aims to reach its target customers through channels (such as magazines, weblogs, social media influencers' channels) that have common target customers.



Informative marketing

Passing the medical information and the product's benefits through medical practitioners. Onboarding medical practitioners such as gynecologists as representatives to promote the products by simply delivering the medical information and product's benefits.



Attending related seminars and conferences

Having a strong presence in seminars and conferences to raise brand awareness among medical professionals.










Target market share

Goal is to capture 15% of the market for these devices by year 5.

HIRING STRATEGY

Examera comprises four founders with diverse expertise and work experience from business to medicine. Hence, the founders are able to handle business development, sales, marketing, product support, and management. Overall, it is projected that the company is able to operate with six employees in the first year of its operation, considering the expertise of its founders.

Positions	Profile	Year 1	Year 2	Year 3	Year 4	Year 5
CEO	 Mrs. Zahra Rabbani	1	1	1	1	1
COO	 Mr. Arta Ariapad	1	1	1	1	1
CMO	 Mrs. Arezoo Hesamifard	1	1	1	1	1
Product Director	 Mrs. Mahshid Fooladi	1	1	1	1	1
Business Development/Sales	 Unspecified	1	2	2	4	6
Software Engineer	 Unspecified	1	1	1	1	1
Hardware Engineer/R&D	 Unspecified	-	-	1	1	1
Total Employees		6	7	8	10	12

With an average salary rate of \$60,000 (CAD) in Canada, the total cost of hiring for the first year is estimated to be around \$360,000 (CAD). The number of employees is planned to double by the end of the fifth year. Apart from the founders who take on CEO, COO, CMO, and Product Manager positions, business development and sales experts and software and hardware engineers for web design, product development, R&D, machine learning, programming, and customer support will be hired to promote and develop the business. External contractors and consulting companies will provide further legal, accounting, and regulatory consultation.

FINANCIAL PROJECTIONS

The following sections explicate the financial projections for the key financial statements of Examera for the first five years.

CAPITAL REQUIREMENT

Overall, Examera requires \$100,750 CAD for its Startup cost. The company requires \$20,000 for Product development costs (designing and building the prototype and the software), \$750 for incorporation costs in Canada, \$10,000 for office equipment, \$5000 for the Canadian e-commerce platform, \$25,000 for Canada Health regulatory costs, and \$40,000 for FDA regulatory costs. The breakdown of Startup costs is provided in the table below.

Startup Costs

Item	Cost
Product development cost	\$20,000
Incorporation costs	\$750
Office equipment & computers	\$10,000
Canadian e-commerce platform	\$5,000
Regulatory cost - Class II (Health Canada)	\$25,000
Regulatory cost - Class II (FDA)	\$40,000
Total	\$100,750

The founders will bring in an initial capital of \$200,000 to cover the general expenses, including but not limited to startup costs, salaries, insurance, legal and consultation fees. We expect an investment of \$75,000 by angel investors and a small external investment (\$30,000) by various government grants such as the Canadian Scientific Research and Experimental Development (SRED) since this project contributes to the betterment of women's health in Canada.

MARKET PRICE AND COST

The market price for the Examera device is \$749 based on the Examera’s features and competitive advantages. There are other streams of revenue through selling the probe for \$8, plate for \$1, and the monthly software subscription for \$19.99 CAD. Examera device, probe, and plate respectively cost \$240, \$2.5, \$0.1 CAD to manufacture. It is projected for the company to sell an average of 78 devices per month, starting from 60 units in the 6th month and ending with 96 units in the last month of the first year.

SALES AND INCOME

The table below shows the projected sales for the first five years. The first year's sale is equal to \$490,849, and this amount reaches to \$3,604,792 by the end of year five. The company is predicted to lose \$76,702 and \$34,591 in the first and second years respectively, due to its initial startup costs and other general business expenses. However, this will turn quickly into profit in the third year making \$111,392 net profit. This trend continues to create \$1,162,502 by the end of year 5.

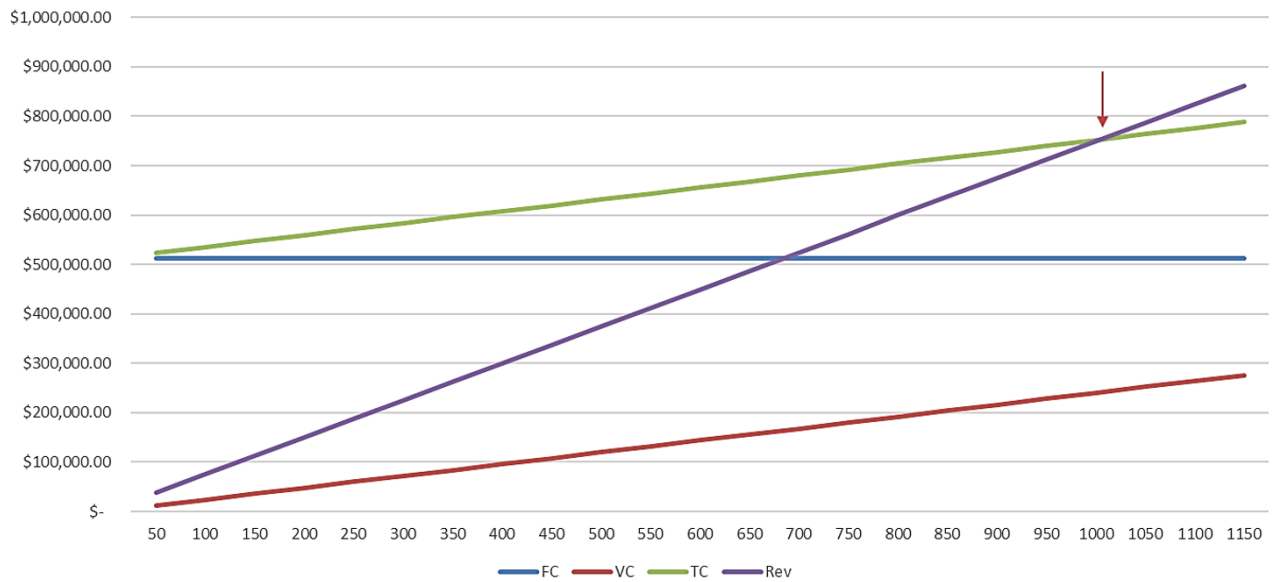
Year	Sales	Growth
Year 1	\$ 490,849	-
Year 2	\$ 736,273	50%
Year 3	\$ 1,178,036	60%
Year 4	\$ 2,002,662	70%
Year 5	\$ 3,604,792	80%

SALES GROWTH

It is projected for sales to grow gradually during the five years projection period. For the first year, it is expected for sales to grow by 50%. This rate is planned to reach 80% in the fifth year, making the total sales value equal to \$3,604,792.

BREAK-EVEN-POINT

Based on the financial projection, it is estimated that Examera is required to sell at least 1005 units of its devices (creating \$752,934.83) to cover all its business costs and start making a profit. Considering the company's sales and startup and overhead costs, it is expected for break-even-point to occur in the third year of operation.

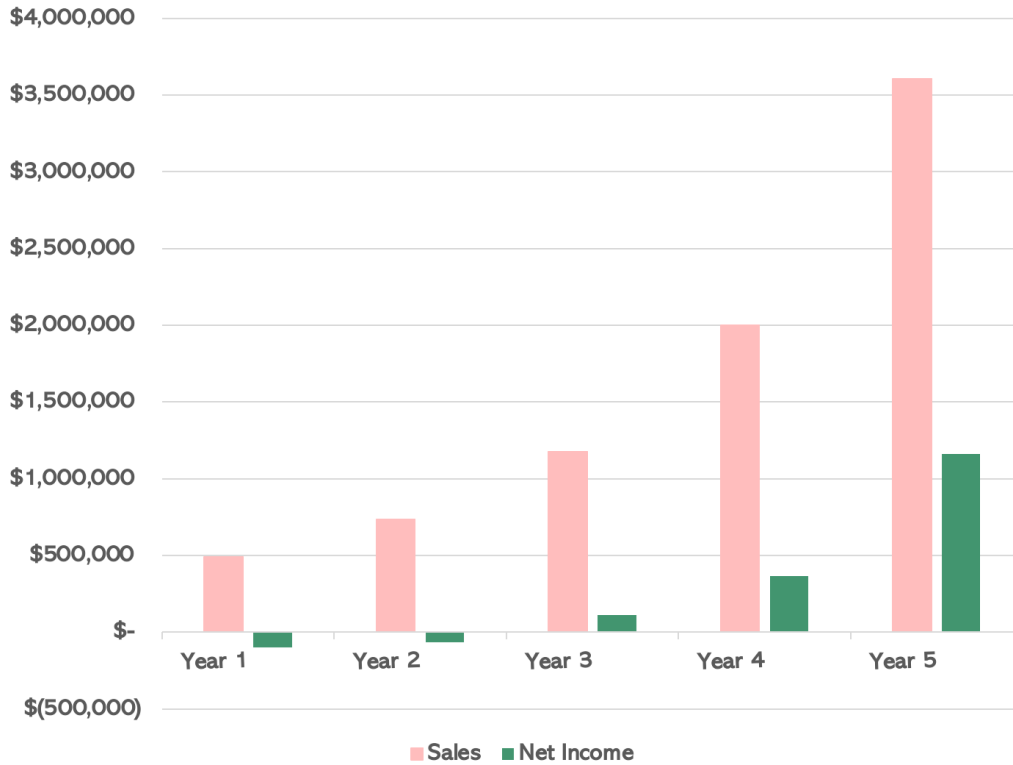


INCOME STATEMENT

The table below illustrates the income statement projection for the first five years of Examera's operation. The cost of goods sold (COGS) or manufacturing costs of each device has been deducted from the sales to calculate the gross profit. Next, the total expenses (including operational expenses) are deducted from the gross profit to estimate the taxable profit (EBIT).

Pro Forma Income Statement	Year 1	Year 2	Year 3	Year 4	Year 5
Sales	\$ 490,849	\$ 736,273	\$ 1,178,036	\$ 2,002,662	\$ 3,604,792
COGS	\$ 147,420	\$ 221,130	\$ 420,147	\$ 756,265	\$ 1,285,650
Gross Profit	\$ 343,429	\$ 515,143	\$ 757,889	\$ 1,246,397	\$ 2,319,142
Expenses					
Marketing	\$ 34,224	\$ 34,224	\$ 34,224	\$ 76,117	\$ 76,117
External Consultants	\$ 6,000	\$ 12,000	\$ 12,000	\$ 12,000	\$ 12,000
Salaries	\$ 360,000	\$ 420,000	\$ 480,000	\$ 600,000	\$ 720,000
General Other Expenses	\$ 9,300	\$ 18,600	\$ 18,600	\$ 18,600	\$ 18,600
Professional Development & Training	\$ 6,000	\$ 25,000	\$ 25,000	\$ 25,000	\$ 25,000
Rent	\$ 12,000	\$ 60,000	\$ 60,000	\$ 120,000	\$ 120,000
Legal and Accounting	\$ 12,000	\$ 10,000	\$ 10,000	\$ 10,000	\$ 10,000
Amortization expense	\$ 2,000	\$ 2,000	\$ 4,400	\$ 10,400	\$ 16,400
Total Expenses	\$ 441,524	\$ 581,824	\$ 644,224	\$ 872,117	\$ 998,117
Operational Income	-\$ 98,095	-\$ 66,681	\$ 113,665	\$ 374,280	\$ 1,321,025
Tax Provision (2%-12%)	\$ -	\$ -	\$ 2,273	\$ 7,486	\$ 158,523
Net Income	-\$ 98,095	-\$ 66,681	\$ 111,392	\$ 366,795	\$ 1,162,502
Gross Profit Margin	70%	70%	64%	62%	64%
Net Profit/Loss Margin	-20.0%	-9%	9%	18%	32%
Avg NPM	6%				

The total tax has been deducted from taxable income (EBIT) or, in this case, Operational Income (as there is no financial or investing income) to calculate the net income or profit after tax. Examera loses \$98,095 and \$66,681 for the first and second years respectively. However, it reaches BEP in the third year and continues to make \$1,162,502 by the end of the fifth year. The average net profit margin (Avg NPM) for Examera for the five-year projection is 6%, which is considered good compared to the industry average for medical devices.



The graph above demonstrates Examera’s sales and net income projection for the next five years. As shown in the graph, the gap between sales and net income reduces over the years as the company starts to make enough revenue to cover its startup and overhead costs.

CASH FLOW PROJECTION

The table below shows the monthly pro forma cash flow statement for the first year, which breaks down into cash inflow and outflow of Examera. Based on the projected cash flow, the total amount of cash inflow for the first year is \$795,849, which comprises the total sales, founders' initial investment, angel investment, and government grant (SRED). It is assumed that Examera does not make any sales for the first five months. The total cash outflow is equal to \$687,694, including marketing, startup, insurance, R&D, transportation, legal and accounting costs, to name but a few. Subsequently, the net cash flow for the first year would be equal to \$108,155 CAD.

SALES FORECAST	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12	TOTAL
Examera						\$ 44,940	\$ 49,434	\$ 53,928	\$ 58,422	\$ 62,916	\$ 67,410	\$ 71,904	\$ 408,954
Subscription						\$ 1,199	\$ 1,319	\$ 1,439	\$ 1,559	\$ 1,679	\$ 1,799	\$ 1,919	\$ 10,915
Accessories						\$ 7,800	\$ 8,580	\$ 9,360	\$ 10,140	\$ 10,920	\$ 11,700	\$ 12,480	\$ 70,980
TOTAL SALES						\$ 53,939	\$ 59,333	\$ 64,727	\$ 70,121	\$ 75,515	\$ 80,909	\$ 86,303	\$ 490,849
CASH IN													
Cash Sales						\$ 53,939	\$ 59,333	\$ 64,727	\$ 70,121	\$ 75,515	\$ 80,909	\$ 86,303	\$ 490,849
Equity Investment*	\$ 200,000												\$ 200,000
Angel investment			\$ 75,000										\$ 75,000
Other Financing/Funding (grants)**			\$ 30,000										\$ 30,000
Total Cash In	\$ 200,000		\$ 105,000			\$ 53,939	\$ 59,333	\$ 64,727	\$ 70,121	\$ 75,515	\$ 80,909	\$ 86,303	\$ 795,849
CASH OUT													
Initial Start up Costs	\$ 100,750												\$ 100,750
Marketing	\$ 2,852	\$ 2,852	\$ 2,852	\$ 2,852	\$ 2,852	\$ 2,852	\$ 2,852	\$ 2,852	\$ 2,852	\$ 2,852	\$ 2,852	\$ 2,852	\$ 34,224
COGS						\$ 16,200	\$ 17,820	\$ 19,440	\$ 21,060	\$ 22,680	\$ 24,300	\$ 25,920	\$ 147,420
External Consultants	\$ 500	\$ 500	\$ 500	\$ 500	\$ 500	\$ 500	\$ 500	\$ 500	\$ 500	\$ 500	\$ 500	\$ 500	\$ 6,000
Salaries***	\$ 30,000	\$ 30,000	\$ 30,000	\$ 30,000	\$ 30,000	\$ 30,000	\$ 30,000	\$ 30,000	\$ 30,000	\$ 30,000	\$ 30,000	\$ 30,000	\$ 360,000
Communications	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 2,400
Bank fees	\$ 25	\$ 25	\$ 25	\$ 25	\$ 25	\$ 25	\$ 25	\$ 25	\$ 25	\$ 25	\$ 25	\$ 25	\$ 300
Office supplies	\$ 100	\$ 100	\$ 100	\$ 100	\$ 100	\$ 100	\$ 100	\$ 100	\$ 100	\$ 100	\$ 100	\$ 100	\$ 1,200
Insurance	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 200	\$ 2,400
R&D	\$ 500	\$ 500	\$ 500	\$ 500	\$ 500	\$ 500	\$ 500	\$ 500	\$ 500	\$ 500	\$ 500	\$ 500	\$ 6,000
Facilities****	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 12,000
Legal & Accounting	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 12,000
Transportation	\$ 250	\$ 250	\$ 250	\$ 250	\$ 250	\$ 250	\$ 250	\$ 250	\$ 250	\$ 250	\$ 250	\$ 250	\$ 3,000
Total Cash Out	\$ 137,377	\$ 36,627	\$ 36,627	\$ 36,627	\$ 36,627	\$ 52,827	\$ 54,447	\$ 56,067	\$ 57,687	\$ 59,307	\$ 60,927	\$ 62,547	\$ 687,694
Net Cash	\$ 62,623	-\$ 36,627	\$ 68,373	-\$ 36,627	-\$ 36,627	\$ 1,112	\$ 4,886	\$ 8,660	\$ 12,434	\$ 16,208	\$ 19,982	\$ 23,756	\$ 108,155
Opening Balance	\$ -	\$ 62,623	\$ 25,996	\$ 94,369	\$ 57,742	\$ 21,115	\$ 22,227	\$ 27,114	\$ 35,774	\$ 48,208	\$ 64,416	\$ 84,399	
Closing Balance	\$ 62,623	\$ 25,996	\$ 94,369	\$ 57,742	\$ 21,115	\$ 22,227	\$ 27,114	\$ 35,774	\$ 48,208	\$ 64,416	\$ 84,399	\$ 108,155	\$ 108,155

BARRIERS TO ENTRY

Below, some of the entry barriers to market for Examera have been identified:

Limited awareness of vaginal self-screening products

Various cultural and social stigmas lead to many women shying away from visiting gynecology clinics. Due to the lack of awareness around at-home diagnostic solutions that can provide accurate results, there have been increasing cases of vaginal infection left undiagnosed and untreated. This fact creates a challenge by adversely affecting the demand for the new products in the market, such as Examera, simply because the consumers are unaware of the existence of the new products. Examera can overcome this barrier by offering informative advertisements and workshops to educate consumers on the benefits of accurate and insightful diagnostic ability of the self-screening products.

High competition

BD MAX is one of the key competitors of Examera that provides an integrated diagnostic system that deals with a variety of diseases outside of vaginal infection. The versatility proves BD MAX's popularity among medical practitioners, making it a dominant player in North America's women's vaginal health-diagnostic market. However, BD MAX only offers an industrial solution that is not household friendly. Examera fills this gap with its self-screening device that can produce faster and more efficient results.

Other competitors such as Natureland and VS-Sense provide a more consumer-friendly type of product in the form of a visually-read swab. These swabs can be easily found and purchased through Amazon or any drugstores at a very reasonable price for at-home use. The convenience and accessibility contribute to these competitor's growing market share in the vaginal swab market. However, these swabs have limited diagnostic ability as they only test for the pH level of vaginal discharge. Whereas, Examera's device has well-rounded features for pH, odor, and color test with AI-based software.

High product price

Examera comes with a non-disposable device, disposable components such as plates and filters, and a subscription-based application. The cost of permanent ownership for the whole package can be quite high for low-income users. This issue can be addressed by giving clinics, gynecologists, and general practitioners the option to rent out Examera to their patients, reducing the affordability issue.

Regulatory hurdles

The Canadian vaginal health self-testing market is governed by Health Canada. In order to be licensed for sale, Examera must prove that its home-use medical device is safe, effective and of quality manufacture. This is achieved through a pre-market review of medical devices (such as clinical studies) and post-market surveillance of adverse effects. The process of getting regulatory approval can sometimes be time-consuming and quite expensive. Thus, entering such a market can be fairly challenging and require high initial capital.

RISK ANALYSIS

Risk management is a cornerstone of every sustainable business. Without risk assessment, unprecedented incidents might take place that can potentially destroy the business. The first step of risk management of any project is to identify the potential risks involved with that business or project in order to plan for them to prevent or mitigate their impact. Below, some of the risks involved with Examera have been listed.

Risks	Probability	Impact	Score	Verdict
1.Major changes in medical regulations	6	9	54	High risk
2.Misdiagnosis	4	10	40	Medium risk
3.Device malfunction (software/hardware)	6	7	42	Medium risk
4.Data breach	6	10	60	High risk
5.Competition threats	3	8	24	Low risk
6.Brand and business reputation damage	5	10	50	High risk

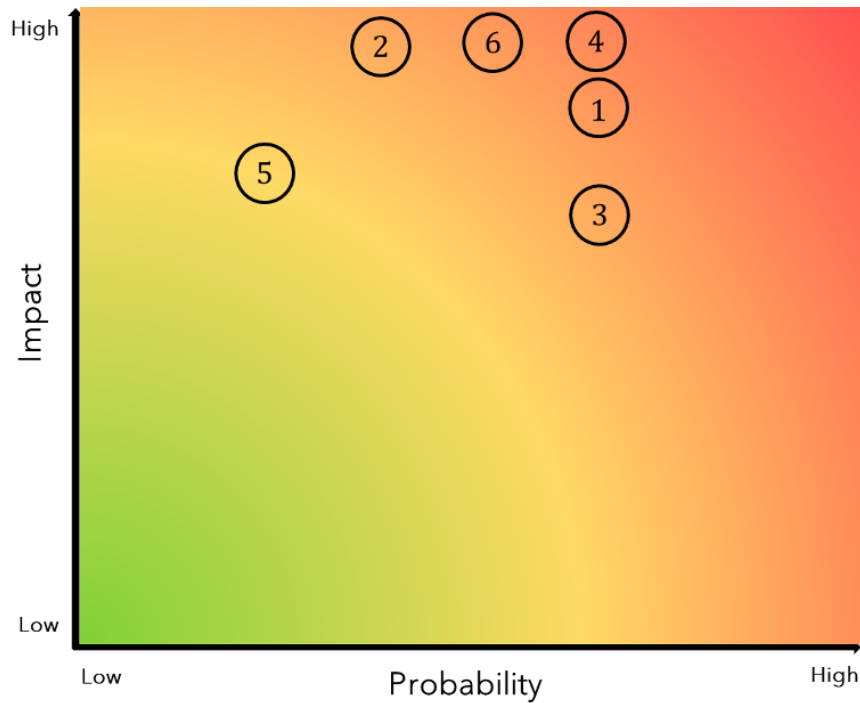
The scale of probability and impact are ranged between 0 to 10 (10 being the highest)

Low Risk (0% - 29%)

Medium Risk (30% - 49%)

High Risk (50% -100%)

Risk Heat Map: low risk (green), medium risk (yellow), high risk (red)



1. Major changes in medical regulations:

The medical device industry in Canada is highly regulated. The Medical Devices Bureau of the Therapeutic Products Directorate (TPD) is the national authority that monitors and evaluates the safety, effectiveness and quality of diagnostic and therapeutic medical devices in Canada¹⁰. Since Examera is a medical device, any changes in regulation can potentially put a halt into its business. To stay above the competition Examera needs to focus on continuous improvement and development of its product. Any changes in the device might require the approval of The Medical Devices Bureau of the Therapeutic Products Directorate. Hence, Examera should always consider the possibility of setbacks in medical disapproval process. Consulting a regulatory expert can be a great respond to this risk.

2. Misdiagnosis:

Examera's accurate diagnosis relies on proper sample collection, accurate measurement of the vaginal-health factors (odor, color, pH), and size of the machine learning (ML) database, all of which are susceptible to error. A small ML database, contaminated filter, plate, or sample, or improper application of the device can all lead to a misdiagnosis of the vaginal disease, which can tarnish the brand's reputation. The impact of such risk is detrimental to the business. However, due to the low probability of the occurrence, the overall risk is measured as "medium." To mitigate this risk, Examera can provide clear instruction in the form of a booklet or an educational video to demonstrate the device's proper application. By gathering data over time, Examera can also increase its ML database size to provide a more accurate diagnosis.

3. Device malfunction:

Examera's software and hardware are both susceptible to breakdown and malfunction. Such incidents can lead to customer dissatisfaction and distrust and, consequently, brand damage. Although Examera is made from quality materials, just like any other mechanical or electronic device, the possibility of breakdown is still high. However, this does not impose a high risk or damage to the company's reputation as these incidents are common, and a quality customer service can bring back consumer satisfaction and trust. Thus, the device malfunction risk is classified as "medium."

4. Data Breach:

A data breach is a "verified and confirmed incident of unlawful access or disclosure of sensitive, confidential or otherwise protected data, including personal health or personally identifiable information, trade secrets, or intellectual property¹¹." The surge in popularity of IoT and cloud-based devices has created an unparalleled opportunity to collect, use, and sell personal consumer information such as financial information and medical data¹². No company is safe from data breach attacks. Some of the most significant examples of data breach happened to giant companies such as Adobe, eBay, Canva, Yahoo, Equifax, LinkedIn, Marriot International hotel, to name but a few. Since Examera uses an AI-based software to connect the patients to their GPs and gynecologists, the risk of a data breach in patients' medical-history data is a frequent and high-impact one. Hence, it should be treated as a "high risk." Examera can mitigate this risk by hiring software engineers to regularly update and improve the Examera's software and adopt common cybersecurity measures such as multifactor authentication to reduce the chance of data breach.

5. Competition threats

As mentioned earlier, the vaginal health self-diagnosis test market has few players such as BD MAX, Natureland, Youcount, etc. However, they are not considered a serious threat to Examera as they lack some of its key competitive advantages such as high accuracy of diagnosis, versatility, fast, affordable, and efficient diagnosis, AI-based software that can give insightful information about women health and collect and build medical-history data. Considering all these factors, the risk of takeover by competitors can be classified as “low.” Nevertheless, Examera must keep an eye on its key competitors in order to keep the level of this risk low.

6. Brand and business reputation damage:

This risk is the result of a combination of risks mentioned earlier such as misdiagnosis, device malfunction, data breach, as well as other factors such as mismanagement, financial scandals, and more. If any of these incidents occur, the Examera’s brand reputation will be tarnished. Since the frequencies of such risks are high and their impact on the business sustainability is critical, this category is classified as “high risk.” By implementing suggested measures such as using high-quality material to build the device, hiring software engineers, regularly improving and updating the software, managing transparency, adopting high cybersecurity measures, and providing instructional booklets and videos, Examera can reduce the overall risk of damage to the brand reputation. Furthermore, it can reach out to communities to promote women’s health and engage in corporate-social-responsibility (CSR) activities in order to create a positive brand image.



EXIT OPTIONS



Company acquisition

The acquisition is one of the most common exit strategies for small businesses. Examera can transfer the ownership of its business to bigger and more established companies in the vaginal health self-diagnosis test market, such as BD MAX. The acquiring firm will have access to Examera's technology and business model, which helps expand the company's reach and gain market share. Other potential acquiring candidates are large manufacturers and distributors of head positioning system and other medical equipment such as 3M, Medtronic, Abbott, to name but a few. The COVID-19 pandemic encourages the adoption of vaginal self-testing kits as consumers want to avoid in-person patient visits. It will be an opportunity for these manufacturers to expand their product line into self-diagnostics kits that also aim to prevent diseases. Ultimately, we are targeting five times the Examera's fifth-year revenue, yielding a potential \$23 million of acquisition amount.



Management buyout

Examera has four founders, all with the necessary expertise in business and medicine. If one or two decide to exit, others can purchase their shares and continue to manage the operations smoothly or hire new employees to take on their responsibilities. Since the details of the company's operations and processes are clear to the existing managers and founders of Examera, the transition of power would be efficient and smooth.



IP licensing

In the current vaginal health self-testing market, Examera has a competitive advantage in its advanced technology that allows for both household-friendly usage and superior diagnostic ability. This makes the product an invaluable intellectual property that other competing suppliers are missing. Examera can license its protected technology to other medical suppliers and manufacturers. This strategy is possible for two reasons. Firstly, there is a growing demand for vaginal self-administering tools such as Examera due to the widespread adoption of home-use medical tests and increasing vaginitis cases. Secondly, there is an existing market where revenues can be enhanced by integrating Examera's innovation into its product. For instance, BD Max can potentially expand its target market to home users by incorporating the user-friendly tools and AI system of Examera into its current industrial device.



IPO

Considering Examera's position in the market compared to its competitors, a high market share is expected in the next few years. With a high market share comes brand recognition. In such circumstances, Initial Public Offering can be a lucrative exit option if the founders decide to liquidate and exit the business. Although this option can only occur in the long-run as IPO is a long and costly process and requires a high level of information disclosure, scrutiny by the public, and transparency.



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