



BiosensUM 2019 Business Plan

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This version of the business plan has been adapted to fit the competition criteria. The plan is composed of three sections ; stakeholder's desirability, business feasibility and financial viability.

The surveys issued in this research have been approved by an ethic comity.

Link for accessing surveys:

Patient: https://hecmontreal.eu.qualtrics.com/jfe/form/SV_8DtcJLekpmYlgjr

Professional: https://hecmontreal.eu.qualtrics.com/jfe/form/SV_3Dina13KX8yd9C5

Stakeholder's desirability

By considering the complexity of the solution offered within this business plan, we will start this one with an exhaustive elaboration of the important theoretical points connecting our biosensor. The quantitative details will follow once everything will be set.

Problem: What is rheumatoid arthritis?

Rheumatoid arthritis is a well-known autoimmune disease causing the destruction of articular cartilage by overstimulating the immune system¹. This disease causes chronic localized inflammation of the joints which leads to pain, swelling and stiffness, limiting the dexterity of people affected by it. It is especially damaging for fingers, hands, wrists, feet, shoulders and knees. It currently affects one percent of the world's population and its prevalence is 2 to 3 times greater among women than men. Older people are also more at risk, with over 46.9% of affected individuals aged 65 and more.

This autoimmune reaction is induced in part by an increased concentration of TNF- α that develops in the affected joints. TNF- α is a cytokine regulating the activity of immune cells and other regulatory cytokines. When overproduced, TNF- α causes over-proliferation of immune cells as well as overproduction of collagen-degrading enzymes in synovial tissue². This results in severe cartilage destruction, causing constant pain and stiffness and may worsen over time if not treated.

The complexity of this disease lies in TNF- α itself. In fact, it is an important mediator of the immune response against any exogenous intruder and its inhibition can significantly increase the risk of infections and

severe immunodeficiency³⁻⁴. It is therefore essential for a patient to be able to keep track of his blood's medication concentration. Too much medication would weaken the immune system, but too few would endanger the cartilage.

Leading Solution

To counter this devastating disease, doctors and caregivers offer all kinds of drugs that can reduce the activity of TNF- α . These different clinical treatments, such as anti-inflammatories (Naprosyn[®], Advil[®], Celebrex[®]), slow-acting antirheumatic agents (methotrexate, Plaquenil[®]), or modifiers of the biological response (Humira[®], Enbrel[®], Remicade[®]), are treatments that can be really effective, but sometimes difficult to control, especially when it comes to modifying the biological response⁵. This last category of drugs is used primarily when arthritis is extremely aggressive. These medications are very effective because they reduce the damage caused by arthritis such as the inflammation responsible for the deformity of the joints as well as the pain. However, these drugs must be carefully dosed since they can harm the immune system⁵.

In our case, we will take a closer look to adalimumab (Humira), a monoclonal antibody that selectively inhibits the action of TNF- α and desensitizes the response to inflammation⁶. This drug is administered by subcutaneous injection at frequencies of about 1 time per week, mainly at the patient's home⁴.

Problem related to the leading solution

The problems related to clinical treatments mainly lie in the difficulty of finding the right medication quickly and efficiently (without resorting too much to the trial-error method) to soothe the patient's pain⁷⁻⁸. Furthermore, since there are a lot of different medications available on the market, it is difficult to prescribe a good treatment with precision⁹.

On the side of adalimumab, it is just as important to be able to monitor its concentration in the patient's blood. Considering its high efficiency, it is even more important to find the optimal dose quickly to avoid causing more problems to the patient. In fact, too much adalimumab could weaken the immune system, making normally harmless infections extremely dangerous, while an insufficient and ineffective dose would lead to a deterioration of the disease over time. Moreover, as the immune system tends to produce antibodies to defend against the Humira when its concentration is too low, it is of paramount importance to be able to control the administered concentration in order not to skew future results and affect the client's arthritis control¹⁰. In addition, although this drug is relatively effective (only 10 to 30% of patients do not respond to initial treatment), between 23 and 46% of patients develop resistance during treatment due to an insufficient dosage of the medication¹¹. It is therefore essential to be able to know the optimal medication for each patient considering that each of them can respond differently to the

treatment. A patient who is not receiving any relevant treatment will experience chronic pain, disability, and possibly even, in some cases, premature death¹². Considering that arthritis is one of the leading causes of disability of the population in Quebec, it is important to provide a fast and effective treatment to the patient¹³.

Problem related to the leading solution: Patient

However, there are several issues that do not allow the client to have adequate services and care to effectively deal with the effects of the disease. With the technology currently available on the market as well as the geographic problematic connecting the patient to the doctor, it is extremely difficult to treat each client correctly. Whether it is by lack of data, lack of specialized caregiver or the distance between patients and professionals, it is extremely difficult to offer a good service to the patient.

From a geographical point of view, a problem that can be related directly to the customer is that there just are not enough specialist doctors in remote areas of major cities as of now. Getting an appointment in those areas can take anywhere from a few months to a few years, which is far too long for patients requiring medical help¹⁴. As evidenced by a survey conducted by the BiosensUM team, 50% of the responding patients wait between one to six months to see a professional. According to Ms. Lacasse, a professor at the University of Quebec in Abitibi Témiscamingue, it is just as difficult to receive medical monitoring in big cities¹⁴.

Additionally, there is currently no product with the appropriate technology offering the possibility to follow the immune reaction of patients. The tests that are currently offered must be performed in professional laboratories and take between 15 and 130 minutes to provide the results (see competitor section). These settings do not allow health professionals to perform a real personalized follow-up and the time interval between tests, if any, does not allow them to make an informed medical decision. Most of the follow-up is based on the client's subjective assessment of the pain. The problem lies in the reticence of patients to share their psychological and physical troubles by fear of what follows, for instance, new medications that would enhance or develop new side effects⁷. On the other side, the preciseness of the symptoms that the patient describes is rarely accurate; they might over or under-evaluate their pain relating to rheumatoid arthritis compared to the reality of the situation depending, for instance, on how they react naturally to pain⁷. Moreover, it is difficult to know if the pain felt by the patient is related to rheumatoid arthritis or to the side effects of his medication. Therefore, diagnosing the state of the patient's disease is a very complicated task.

The last major problem related to patients is about the lack of psychological help they receive by the different caregivers. According to the research done by *King's College Hospital NHS Foundation Trust*, the priority

of a patient living with rheumatoid arthritis is to decrease the pain they suffer, to reduce the progression of the disease, to be able to achieve daily tasks normally and to be able to live like everyone else in society¹⁵. However, several patients also demonstrate a stronger need for the psychological support offered by doctors and nurses. In other words, patients want to feel listened and understood by caregivers¹⁵. With the problem regarding the distance between the patient and the professional, the technologies and especially the number of professionals available to treat the disease, it is difficult to remedy this lack of support. It becomes difficult for patients to feel understood, listened to and supervised. The fact that the patient does not have a good constant follow up about his illness, mainly because of the lack of professionals available for them, lead to a misunderstanding of their own situation. The fact that they don't the progress of their disease makes it even more stressful for them ¹⁵.

Problem related to the leading solution: Professional

In addition to harming the care and services received by patients, the issues surrounding the treatment of the disease make the work of professionals much more difficult. They must put more effort and energy into providing the right service for patients. As their primary goal is to alleviate patients' primary concern, the pain, professionals face many challenges at the same time, such as a lack of reliable tests to objectively assess the condition and course of the disease ⁷.

One of the main issues faced by professionals dealing with the treatment of the disease is the complexity of collecting enough data to understand and evaluate the immune response of the patient to the treatment. As it is expressed by AMIA Annu Symp Proc, "All the physicians agreed that more information about the time between office visits would be helpful in managing RA."⁷. In order to correct this gap, some professionals propose to patients to keep a journal of their symptoms up to date in order to obtain a more in-depth data set. However, this method also requires an extremely long subjective analysis that the professionals don't have the time to accomplish. Some clear and much more frequent follow-up would allow rheumatologists to assess patients more precisely so that they can prescribe the appropriate treatment more quickly and with more confidence⁷. As it is explained in the section related to the patient, the follow-up of the disease is very infrequent and difficult to do. Thereby, the patient's situation can vary greatly between each encounter. The trial-and-error method thus remains the most used, resulting in an inestimable loss of time for caregivers⁷.

We know that the lack of data is a problem facing professionals, but the most important issue is the lack of objective data. As explained above, it makes the work of professionals much more difficult. Some of these professionals believe that the information provided by the patients is not always representative of their actual

condition, which can induce errors in the recommended medication dosage. Rheumatologists routinely use self-report surveys in which patients assess their levels of pain. However, like we said before, some patients are more resilient than others since pain is a subjective experience, which introduces errors in the results of the survey. It is also important to point out that fibromyalgia, among others, is a frequent comorbidity of rheumatoid arthritis which induces additional pain that is not due to the latter. This may lead to a higher dose of RA medication which amplifies the risk of adverse side effects from the medication, without having a significant therapeutic effect. On the contrary, other patients can become tolerant to the pain and not report their levels of pain in an objective manner since they report lower levels⁷. The lack of objective data thus leads to a discrepancy between what the patient feels and what the professional wants to analyze.

Additionally, as professionals cannot really know the patients' assiduity at taking their medication, it is difficult for them to know if the patient is constant or not with his medication. Caregivers often encounter patients that consider side effects more worrying than the actual joint destruction and inflammation caused by RA and who end up quitting the treatment by themselves. Therefore, rheumatologists need a tool that allow them to be sure that their patient took their medication at the recommended dose to be able to follow the necessary procedures otherwise⁷.

Problem related to the leading solution: Government

Like we know, healthcare in Quebec and Canada is public and therefore almost entirely subsidized by the provincial and federal governments. It is therefore important for them to treat each disease the fastest that they can to minimize the cost of the treatment related to the diseases themselves and their side effects. In the case of rheumatoid arthritis, it is just as important to treat it quickly because it can affect other organs much more important in the long term. For example, without effective treatment, rheumatoid arthritis can affect the eyes, nerves, skin, and lungs. Even in extreme cases, joint destruction requires reconstructive surgery. Thus, the treatment of rheumatoid arthritis is essential as it can slow down the destruction of joints and prevent the need for surgery and any other specific treatment¹. Considering that these long-term effects require additional care, it is certain that controlling the disease as soon as possible would allow the government to realize significant savings.

In fact, according to the study made by Ohinmaa in 2014, the average annual costs associated with rheumatoid arthritis per patient in Canada, in addition to the drug, is \$ 5,531. This includes \$ 2,349 in hospitalizations, \$ 1,716 in appointment with the doctor and \$ 1,465 in emergency room visits¹⁶. The authors concluded that the costs associated with rheumatoid arthritis could be reduced by aiming for better disease control and maintenance of joint function.

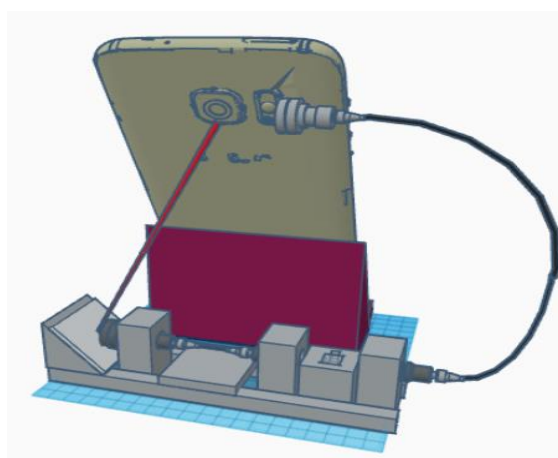
Considering that the average annual treatment cost per patient is \$ 17,160¹⁷ and that of this amount, \$ 5,531 is a result of poor management of the disease and its side effects (hospitalization, medical examination and cost related to hospital rooms¹⁶), it is important for the government to limit these costs as much as possible.

Overall, they estimated that the direct healthcare cost of RA in 2010 in Canada to more than \$ 2.4 billion and these costs are expected to increase cumulatively to reach almost \$ 95 billion within the next 30 years (in 2010 dollars). Similarly, the indirect costs are estimated to be more than \$ 3 billion and are expected to increase cumulatively to reach almost \$ 163 billion within the next 30 years (in 2010 dollars)¹⁸ (Annex 1).

According to the Arthritis Alliance of Canada \$ 1.7 billion could be saved in cumulative direct healthcare costs over 10 years and over \$ 5.1 billion over 30 years (2010 dollars) additionally to \$ 11.6 billion in cumulative productivity losses over 10 years and over \$33.7 billion over 30 years (2010 dollars)¹⁸ if all new cases of RA and all people living with RA had access to early and appropriate treatment. It is therefore extremely important for the government to find a quick solution in regard to the monitoring of the disease in order to reduce costs. It's possible to see the contribution of the government to our enterprise in the financial section below.

Our solution

The BiosensUM company aims to develop an innovative biodetection system to determine the concentration of Humira (adalimumab), the drug discussed earlier, in the blood of patients. In other words, this biosensor allows quantification of the drug from blood plasma in approximately 4 minutes while using less than 20µL of plasma, which is less than a drop of blood. This instrument is easy and safe enough to allow everyone to use it. It has the advantage to be manipulated without the help of a professional. In fact, our biosensor connects directly to a cellphone in order to use the camera to collect the various data relating to the concentration and to perform the data analysis.



Competitor

Company name	Test name	Time to obtain results
BiosensUM	LightUs	5 min
R-Biopharm AG ¹⁹	RIDA®QUICK ADM Monitoring	20 min
BÜHLMANN ²⁰	LF-TLAD25	15 min
Sanquin ²¹	MabTrack level adalimumab	130 min
apDia ²²	apDia Adalimumab ELISA	100 min
Theradiag ²³	LISA-TRACKER Adalimumab	120 min
Dynacare ²⁴	ADALIMUMAB	20 days ^a

^aThis is the time that it takes to send a sample to Dynacare and to receive your result. The time of the test itself is, however, unknown to us

Competitive advantages

Inexpensive

Our device has the characteristic of being designed in an innovative way that allow us to minimize its selling price. By directly linking the device to the cellphone of the customers, we can reduce the material needed for the fabrication of the biosensor. This advantage allows us to reduce both the sale and rental price, providing a wider range of customers, patients and professionals, while offering a better profit margin opportunity. The different costs can be found in the financial section below.

Accessibility

Our biosensor offers the possibility to be accessible either at the office of the professional or directly at the patient's home. Its dimensions and the way it has been programmed offer the possibility for the doctor and the patient to use the device during a routine consultation as well as in the patient domicile between the different appointments. This makes it possible to considerably increase the data analyzable by health professionals. Furthermore, it helps to relieve the health system by reducing the necessary encounters between the patient and the doctor. This advantage is considerable since most part of the substitute products absolutely requires the assistance of a caregiver in addition of having to be done directly at the office of the professional due to their size and the difficulty to use them. In addition, as evidenced by a survey conducted by the biosensUM team, 87.5% of the responding patients would be inclined to use a device that allows them to, as it is currently done with the biosensors related to diabetes, monitor their medication directly at home and without the help of a professional. Likewise, 71.4% of the responding professionals affirm that they would be interested in knowing the blood's concentration of Humira of patients between their appointments. This advantage also helps the psychological side of patients by allowing them to track the progress of their disease on the mobile application directly in their home, which can help them to reduce the stress about their knowledge of their situation.

Easy to use

Since our product can be employed by professionals as well as by patients, it must be easy to use. The biosensor will thereby be usable directly on a mobile application in the cellphone of the patient. As you can see with the survey realized by the BiosensUM team, 70% of the responding patients (from 18 years old to more than 66 years old) would be interested in using a device like ours that would be connected directly to their cellphone. A guide is also available to tell the user how the unit works. This guide also includes some advice on exercises that

patients could do between their meetings with their health care provider. *You can see what look like our user-friendly application in the section **sales & marketing** under sales.*

Fast to use

Contrary to other tests available on the market, our device has the characteristic to perform the test in less than 5 minutes. It is therefore not at all cumbersome for the patient or the caregiver. Patients can therefore perform the test at home without wasting their time, which would probably discourage them from using the device. Furthermore, 66.6% of the responding professionals to the survey made by the BiosensUM team believe that getting faster results of concentration will certainly improve the effectiveness of the treatment.

Originality

As explained above, our product is something completely innovative that allows the company to stand out from the competition while creating an attraction for the product. This way of proceeding provides a major differentiation aspect to the product.

Heavily subsidized company

On the financial side, the company is fortunate to be located in Quebec, giving it access to considerable government subsidies. Compared to some countries, Canada heavily subsidized research and product development like ours in the medical field. We have the advantage of being supported by the federal and provincial government during our research and development. *You can see those subsidize on the financial section below.*

Business feasibility

This section includes :

- The *action plan*
- The *sales and marketing plan*
- The *operating plan*
- The *Human ressources plan*

These sub section will explain the key resources, activities, partners and as a coherent view with the value proposition.

Action Plan

It is important to know what are the crucial steps our company needs to take in order to reach its full potential. Therefore, we elaborated an *action plan* that act as a precise timeline describing the key phases, we plan on engaging in. This schedule could be modified if new information is to be added to our current understanding of the situation.

Phase	Goal	Deadline
1a: Research & Development	<u>Developing a functional biosensor for rheumatoid arthritis:</u> During this period, we will work on every aspects of our offering to make sure everything is set to give the most convenient customer experience possible. The goal is to develop the product to its most final form in order to meet the client's needs as soon as possible. This goes from working on the light source connectability to the mobile app features going through developing the most convenient cartridge system.	01-2020-01-2022
1b: Obtaining the required certifications	<u>Obtaining a serie of certifications to have the right to sell our products:</u> FDA (United states),Health Canada (Canada),marquage CE (Europe), PMDA (Japon). And some more specific tests such as EP7 protocol (test regarding the interference of other drugs with adalimumab.	01-2020-01- 2022

1c: Funding	<u>Obtaining key financial partners:</u> Many public organisations are willing to lend or subsidize substantial amount of money to help us developing our product in the early moments. As an exemple, the economy and innovation section of the government of Quebec is ready to evaluate business with a strong business plan and willing to move forward with their products ¹ R&D Programme PARI - NRC, Partenariat avec Université NSERC, CQDM, Ministère Economie, Desjardins programme entreprises démarrage	01-2020-01-2022
1d: Incorporate the company	As many organizations (incubators, banks, organizations) require this statut in order the be eligible to their services. It is also easier to operate that way since it gives a series of advantage such as tax cuts and restricted responsibilities for the owners. It would cost around 1500\$ CAD ² .	01-2020-01-2021
1e: Patenting the technology	<u>Protecting intellectual property</u> : Since developing such a technology takes time. We will file for a technological patent in order to keep the intellectual property internally and prevent any big companies to overtake our technology. This will facilitate any grant application, but also enhance all collaboration. The relative cost of a patent it aound 7000\$	01-2020-01-2021
2a: Trial period	<u>Commercializing the product only for rheumatoid arthritis to preselected users:</u> After having a functional product to test and the required certifications, the next step is to start evaluating the suitability of our technology under real circumstances. From there, we will be able to spot what needs to be improved and what is working properly.	01-2022-06-2023
2b: Partners	<u>Developing strong relations with partners:</u> The association responsible to distribute the products through the public health system and the main players in the private sector. For more details on potential clients; please refer to the section; <i>Sales and marketing plan ; Clients.</i>	01-2020-01-2023
2c: Improvements	Implementing additional features and applying corrections of the newly detected issues: Analysing the results of the usage of our detection system on the quality of life of the patient and the practicality for the doctors.	09-2022-continuous
2d:		
3: Exploitation of RA value proposition and R&D 2	<u>Developing other tests:</u> Versatility of the testors is an important factor to consider since there are various drugs (other than adalimumab) used in the AR treatment. Furthermore, adapting the testor to other illness increase the value of acquiring one since it could than be used for many tasks.	01-2023
3a: Regular operation	<u>Generating continuous revenues from RA sales (tester and cartridges).</u>	01-2023-continuous

¹ Économie et Innovation Québec., Obtenir du financement. P.1.

² Registraire des entreprises du Québec., How to constitute an open society. P.2

	It's also about adapting our administrative capacities to handle the increase in sales. Make good use of an integrated information system as a database for an interactive analytic dashboard.	
3b: R&D 2: Alternatives Drugs	<p><u>Developing tests for substitutes molecules to Humira:</u> SPR technology is an accurate technology for detecting antibodies. Other antibodies used to treat arthritis are given depending on the type of arthritis and other medications given at the same time. Adalimumab is the most administered for treating rheumatoid arthritis. The target is what the antibody binds to in order to stop its action.</p> <p><u>Target:</u> TNFa; infliximab, golimumab, certolizumab, etanercept <u>Target:</u> IL6 tocilizumab ;</p>	01-2023-01-2025
3c: R&D 2; Other illnesses	<p><u>Antibodies in other diseases:</u> ex : Breast cancer.</p> <p><u>Biomarker:</u> A biomolecule we measure has to determine a person's physiological condition -HER2 monoclonal antibody is overexpressed in certain forms of breast cancer and helps decide what treatment to give.</p> <p><u>Treatments:</u> Cetuximab (for triple negative breast cancer).</p>	01-2023-01-2027
3d:		
4: Public market	<u>Commercialization to the whole public:</u> This is where we try reaching out for as many consumers as possible.	2025
4a: Marketing	<u>Setting up an efficient marketing campaign:</u> Dragging attention towards our technology is a crucial factor in order to drag and increase. sales	2025
4b: Commercial production	<p><u>Acquiring the assets needed for commercial production:</u> Lower our cost of production at this state can lead to substantial economies of scale. List of the material included</p> <p><i>Please refer to section : Operating plan for more details.</i></p>	2025
4c: Acquisition of a private location	This include the whole range of assets needed to be fully operational by ourselves.	2025
4d: Additional funding	Additional funding is necessary to finance the expansion of our activities to the international scene.	2025

Sales & marketing plan

Marketing plan

This section will describe how we plan on entering the market. The objective is to start with the provincial market of Quebec where we found the main providers in terms of medical equipment for public services. After, we will expand our activities to the rest of Canada and the U.S. Finally, after developing more tests and gathering the necessary resources, we will try to reach international markets such as Europe and Asia. In this section, we will discuss about how we plan to access our possible clients and how we will distribute our products to them.

Clients

The products we created addresses a problem that is relative to RA patients. Those are the one whom need help with the pain caused by the illness and seek advice mainly through their doctor. They are our primary clients and we need to adapt the characteristics of our tester to their needs . Another client of ours are the professionals involved in the process of treating the disease. We also adapted the characteristics of our offering to their needs. (*see section ; Stakeholder's desirability*).

But the direct client with whom we will do business with are the various **medical distributors** in the area. By interviewing André St-Amant³, a medical distributor, we learned the main distributors of our technologies for Canada and even one for the U.S. He told us that “ *Achieving partnership with those companies could take several years but is definitely worth since they can bring visibility to our product everywhere, they have connections*”. They are often the ones that win call for tender offers in the public sector because of their expertise and their reputation

Here is a list of the main distributors in the area:

SigmaSanté (Québec)
GACOQ (West of Québec)
GACEQ (Est of Québec)
HealthPRO and Medbuy (west of CAN)
McKesson (USA)

³ ST-AMANT, André. Distribution of medical device in Quebec (*interview*). P.1

In order to have a chance of being selected by them, the first step is to ***be approved by the government*** by sending them as complete submission that include: the product we wish to sell, the proposed pricing and much more details⁴. They will then evaluate our case and tell us if we are allowed or not to distribute our product.

After being approved by the government, we need to have a very good call for tender submission since it is that way that they select their clients. The Institut du Quebec states ‘ ‘ *Price remains the primary factor evaluated in call for tender in Quebec* ’ ’⁵. But the price is not the only aspect that is being taken into consideration. In fact, I.N.E.S.S the national institute of excellence in health and social service provide guidelines on the various criteria a good submission needs to consider⁶. Those criteria include: Illness description, various certifications such as the *Medical device license* whom is delivered by Health Canada concerning rules regarding medical instruments, pitches on the usefulness of our services for the population

and much more. For submission relative to integrated supplying, Health and social service Canada provides an even more complete set of norms to consider⁷. We will therefore focus primarily on fulfilling those criteria to the best of our competency to then apply to offers related to RA detection.

Other alternative; private sector

Another way of distributing our products is by directly reaching the secondary clients, the professional, whom procuring decision relies directly on their hands. This is the case in private clinics where the decision of which medical tool to use is often taken by the board of direction. This board is most of the time constituted by doctors and professional in the clinical field. To reach those potential clients, we would hire a part-time seller the first year whom job would be of promoting the company through the varied point of access (*see section : publicity and promotion*).

Other alternative : Direct sales to the patient

Even though this is not a common way of selling medical devices in Canada, we would always stay open to sell our product directly to the end customer if the occasion arises.

⁴ Santé et services sociaux du Québec, *Doing business with the health and public services network*. P.1

⁵ Institut de Québec., *Adoption of innovations in healthcare in Canada*. P.1-39.

⁶ I.N.E.S.S.S., *Guide of call for tender*. P.1-17.

⁷ Santé et services sociaux du Québec, *Doing business with the health and public services network*. P.1

Distributor (*delivery*)

When the commercial activities will be undergoing, we will need to make sure our products can be delivered to the end customer. Insuring durable partnerships with delivery companies is key to a successful distribution system. It is also a key element to customer satisfaction since respecting delivery date can be very important for some of our clients.

Local

Drugstore: The main distributor we would like to have is pharmacies. Indeed, there are many of these stores scattered everywhere in the country and most of them are located in strategic area. Our plan is to sign deals with as many of them as possible. The agreement would be that they have our products in stock and we pay them a certain amount. That concept would allow the patient to have a prescription from his doctor that says he can pick up both his device and chips at the local drugstore. It would increase our efficiency and lower the cost of distribution since every customer would be grouped to a store.

Delivery companies such as UPS and Fedex: To respect the drugstore concept, we also need a distributor that delivers them the goods. For every store, we would estimate the demand for our product and then ship one big delivery of it every month. To execute that delivery, we would sign an agreement with companies like Fedex and UPS depending on which one offers the best services.

International

In order to increase sales potential, we want to open ourselves to the international market when it becomes a good idea to do so. The main way we planned on doing that is by doing business with the exportation ministry of Canada. They have a program that helps small businesses do international trade by providing them with the contacts and facilities to operate on overseas markets. The state also allows subsidy for small businesses that wish to do international trade. The subvention program is called CanExport and can give up to 50'000\$ CAD⁸.

⁸ Gouvernement du Canada., *Exporting funding*. P.1

Sales

This section is related to our plan to generate sales. Sales are a crucial indicator when it comes to a business profitability. Therefore, we will surround of all the tools necessary to drag as many customers as possible. In this section, we will discuss the set of products and services we plan on offering, pricing, publicity and promotion and our customer service policy.

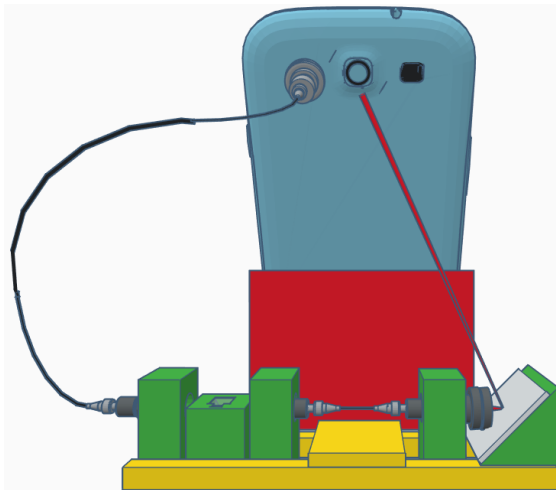
Product and services (*our unique value proposition*)

Here a brief description of our offering.

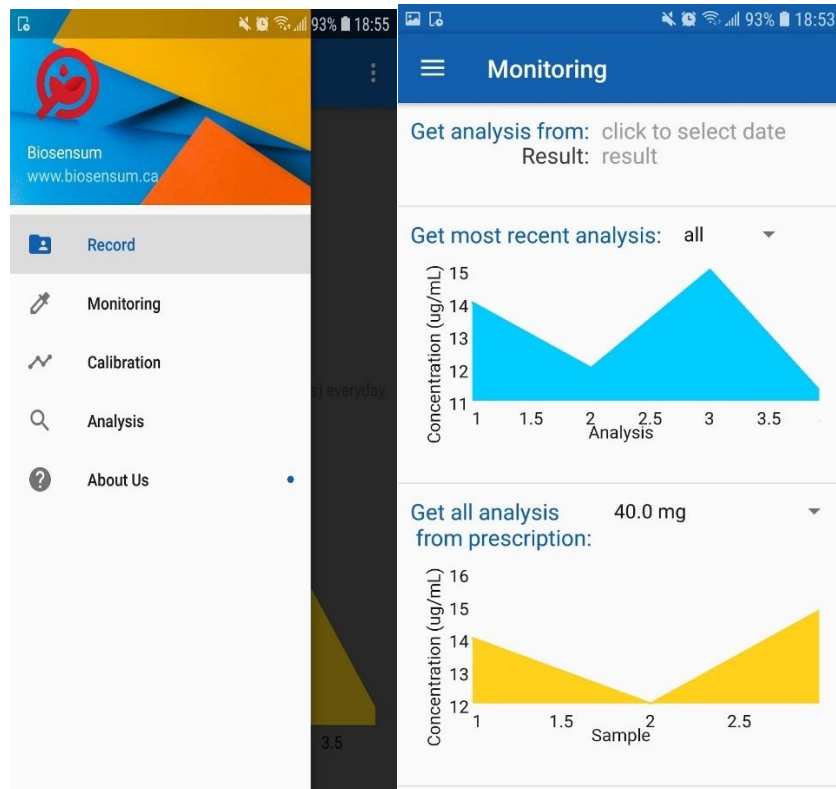
Products

Device: A fast and reliable detection system that:

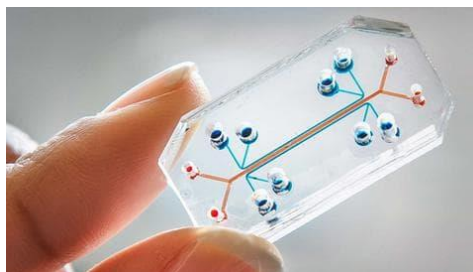
-Use a cell phone as a detector: This feature reduce a lot the cost which is the primary criteria in public call for tender.



-Has an integrated software: An application that can show the obtained results as well as send them to the doctor in a matter of seconds. The app contains : A client resume, a picture mode where it is possible for the patient to diagnose himself and a section where the company is described. Obviously, we work on adding more features in the near future such as a doctor mode where the doctor could access the data remotely by simply login in the system.



Microfluidic chips: An easy to use and versatile device that collect the blood and execute the chemical reactions needed to determine the concentration of adalimumab in the human plasma.



Services

Customer service: We plan on hiring employees to answer customer questions, whether it comes from the medical distributor, the professional or the patient. We also plan on having a mobile team that could go fix important issues, do periodic check ups, etc. (Also see : Customer service policy)

Pricing policy

Price plays an important role on the margin we will be able to make on our sales and ultimately the net income at the end of the year. Finding the exact price a customer is ready to pay for something is very hard since it takes knowledge of his propensity to spend and other variables that are, most of the time, hard to determinate. This section will discuss how we determined a *standard unitary price* and the *strategy* we will undergo when it comes to establishing a price.

Price determination

In the section *business feasibility: Sales*, we did some estimation about how much AR cost for the Canadian society in terms of direct and indirect sales. Based on those assumptions, the cost per patient for the society *we could save* is around **16'068\$**. Therefore it is plausible to suggest contract that could range between that value since using our products would resolve in a gain for the customer that buys it. Obviously, a lot of the amount would be subsidized by the government so that the final price for the customer (doctor or patient depending on the distribution strategie) would be around **5'623\$** per year.

Pricing strategy

We have the expertise to develop a competitive pricing strategy which is based on the data we are able to collect or obtain from concerned parties.

Price discrimination

The price we propose would be adapted to whom we are doing business with. Indeed, if it's a huge distributor, then we would probably ask for smaller margin since he would be able to provide us with a lot of volume in terms of sales. On the opposite, if it's a one time purchase, we would ask for a bigger but reasonable amount.

Personalized proposition

Part of our pricing strategy comes the option or leasing or buying the device. This enable the client to have two options for acquiring the device. He could lease it temporarily to see it's effectiveness than decide to buy it.

Publicity and promotion

Promoting the company on the public scene is often how you drag new customer and spark public attention. Assuring our presence to key events is crucial to obtain visibility and increase the reputation of our brand. In this section, we will discuss the various methods we plan on using to achieve those objectives.

Publicity

Presence in medical events

Events related to arthritis are a good way of promoting the products our company offers. Indeed, we would target specific medical events and buy a kiosk there. Also, the fact that our company is composed of university student gives us the chance of accessing free conference. There, we can present our project in front of many doctors and health professionals from different hospital. This was actually done by one of our members this year in an event at Sainte-Justine Hospital in Montreal.

Organizing conference

According to André St-Amant, another common way of putting the emphasis toward our brand is to organize conference where we discuss subjects related to AR and also suggest our brands on the side. This would require hiring a public speaker, paying the fees needed to be registered to the event and other specific fees. *EmedEvents* is an organism who advertise event upcoming in the Quebec area. We would probably ask them or/and one of their competitors to advertise our conference if we were to organize one.

Scientific journal

We can either publish in professional journal where we could pay to promote our product or even publish in university journal where it is close to be free and also very popular for nearby professionals. This is also a great way to generate word of mouth since a paper is easily shareable.

Promotion

Researching call for tender opportunities and applying with aggressive offers

We will strategically give discounts and other advantageous perks if needed in order to sign contracts. The perks could take the form of longer time for repayment or even extra products for the same price. Another thing we could do to initiate a first sale is to give a free trial period where the patient gets to try the product for free.

Bundling

We could offer different bundles of product to choose from where buying more than 50 devices gives a decrease in marginal price.

Discount

We would propose periodical discounts to stimulate sales. Also, we would propose a discount for the client that will pay quickly. This method of reducing the price will certainly attract some customers. In fact, this promotion will be divide in 2/10, n/30 meaning that customer paying in the first 10 days or before will have a 2% rebate and the other will be funded by us for 30 days.

Customer service policy

Bad customer care policies are sometimes a cause of financial difficulty because of the poor client retention rate that comes with it.

Solving the problem fast: When the client is not able to solve the problem solely with the use of the guidelines, we provided him, he will be able to call us through the customer service line. From there, one of our representatives will offer a personalized service oriented to satisfy the patient needs and answer his worries. Finally, if its a problem we can't solve through the phone, one of the technicians will reach the working place and then take care of the problem.

Monitoring the quality of our services : Evaluating the customer satisfaction after requesting us something helps locate potential problem with the way we provide help. Constant monitoring can be done by using an interactive dashboard that is integrated into the information system. It would allow us to know basic stats about a situation such as the number of complaints received for a given month.

Operating Plan

Our unique value proposition needs to be supported by well structured means of production to insure it meets client's expectations. In this section, we will describe the various investments we plan to make in order to elevate our production to an international level. In order to be fully operational, BiosensUM has to get through different stages of development⁹ which require various needs in term of localisation, material & equipment, research & development and other expenses.

Location

From Phase 1 to Phase 3: Incubator

During Phase 4: Private location

Incubator

In Montreal, there is a lot of incubators for science business such as *citébiotech*¹⁰ are constantly looking for new start-ups ready to develop their products at their place. It could be a great advantage to apply for one of those as soon as we are ready to start phase 1 (*research*), to beneficiate from the many advantages that can provide that location. Indeed, you can get *support from the community* there. It is a great way to *increase the network* and possibly get new partners. Also, it creates substantial gains it terms of *cost savings*.

Acceptation

The hard part of the process is the provide them with a solid business model on which they can base themselves to evaluate our profitability potential. For us, providing them with these informations won't be a problem and we are confident on getting accepted with the model we have. Candidature are often evaluated by a selection committee based on criteria related to marketability and scientific potential.

Schedule

The plan is to stay there until we generate enough cash flows to operate independently. It is possible to sign contracts ranging from a duration of one to 5 years. We will aim for a 3 years contract.

Cost

For the first years, we are lucky to have access to a free laboratory at the Concordia university named District 3. Indeed, this laboratory provides us with all the basic equipment needed to execute the production. This chargeless location would probably lead to a saving of about **2500\$-3500\$/CAD**¹¹ per month that would have been engaged if we were to operate independently.

⁹ See business plan section ; action plan

¹⁰ Cité Biotech., *Incubator*. p.1.

¹¹ See : <http://www.lokahipacific.org/compare.html>

Private location

After fully developing our products (*detecting multiple drugs given as treatment against arthritis as well as other tests for similar illness*) and generating sustainable incomes from selling the device and cartridges, we will look for our own private location. For the first few years, we will rent an easily accessible laboratory on the urban region with no equipment included. In fact, because incubators are only available for start-up, we would need, after the first 3 years, to sign a lease with a private location.

Schedule

It is hard to say how much time we will operate by leasing a place or when will it becomes more advantageous to acquire our own building. However, we will definitely do a yearly analysis of the situation to determine if it's better or not to invest in those assets. If everything goes well, we will, during the fourth and fifth year, rent a private location before acquiring our own emplacement to reduce the cost.

Cost

The average leasing costs will be from 1000\$-1500\$/CAD per month, whether about 10\$ per square feet. However, this price only include the laboratory. We will therefore need to buy every equipment and material to run the lab. Those cost will need to be review at this time depending on the demand of the product.

Material and Equipment

We need to have access to every tool needed to execute our work properly. It is crucial for us to develop key partnerships with suppliers who can provide us quality stocks for a lower price.

Suppliers

Having the right suppliers is key to obtaining low cost/ high quality material. Especially for piece that are often used in the production, we need to carefully select whom we're doing business with. At the moment, most of our products come from *Thorlabs* a well establish suppliers in the medical field. We will expand our list as the need for new products or better prices increase.

Technology

Integrated management system

It is important to perform regular follow-up on the usage of our resources and insure proper protection of these assets. Therefore, we armed ourself of a powerful integrated management software which will save all the data relative to the stocks, equipment, sales and much more.

Analytic dashboard

Linked to that management system is a dashboard that would be programmed to show key indicators to watch for such a profit for the month, inventories, ongoing orders, etc. This will help us monitorate every aspects of the business and set goal to attain.

Equipment - Incubator

While operating within the incubator, most of the required equipment will be available to us costless. The only thing we will need to purchase is the stocks related to goods production such as the substance needed for the chips and the ones needed to build the apparel. Material provided by the incubator include laboratory furniture and chemical fume hood, type 2 reverse osmosis purified water, natural gas, nitrogen gas network, network vacuum system, emergency electrical circuits, sophisticated ventilation and safety, biomedical and chemical waste management system¹². The rest of the equipment needs to be acquired by us, but most of our stocks will be impartialised to start off which limits the amount of equipment needed.

Equipment- Private location

More equipment will be acquired at that stage to fulfill the needs that were previously filled by the incubator. Furthermore, we will need administrative equipment and stock. *For the list of additional material we will acquire please contact us @ BiosensUM. gmail.*

Material (Stocks)

Most of the stocks we will acquire is going to be used to produce the microfluidic chips and the machine. For more details on the list of items needed to produce each of them, please refer to section : *Financial viability ; Cost of production.*

Research and development

A big part of our fund will be reinvested in research & development especially in the early stage where we will aim to develop a reliable detection system about the concentration levels of adalimumab. Here is a list of the research we plan on executing in order to obtain reliable analysis and more type of tests.

¹² Cité Biotech., *Incubator*. p.1.

List of researches to execute includes :

Name	Type	Description	Due date	Estimated cost
Alternative tests for arthritis	Research	Finding how to do the new tests	01-2023-01-2025	150000\$
Alternative tests for arthritis	Development	Developping new surface receptors	01-2023-01-2025	150000\$
Tests for other related illness	Research	TBA	01-2023-01-2027	300000\$
Tests for other related illness	Development	TBA	01-2023-01-2027	300000\$

Production of the chips and device

Here is an overview on how we plan to assembly our products.

Device

Our optimized 3D print can be printed on any big enough 3d printer. The assembly part takes only 10 minutes and consist in connecting the optic fiber in the collimator and installing the collimator in the right holes.

Chips

Glass prism are coated successively with Chromium ($\approx 3\text{nm}$) and Gold ($\approx 50\text{nm}$) using a metal evaporating system. Gold coated prism are functionalized using a peptide (3-MPA-LHDLHD-OH) in a way to form a self-assembled monolayer (SAM). This allow a great increase in sensitivity and precision toward adalimumab. These prisms can be stored in the dark before use. To start an analysis, the microfluidic chip is than glue on top of the prism and the sensor is than functionalized with the receptor, TNF- α . The surface is passivated with blank plasma and is now ready to use. This procedure takes 30 minutes.

Human resources plan

Selecting the right set of expertise is a crucial aspect to consider when it comes to having efficient operations throughout every activities BiosensUM must engage in. Careful and skilled hiring policies needs to be implanted to make sure every scale of the business is filled with qualified personnel. This section will list the various competence needed to be fully operational and provide guidelines on key criteria's surrounding human resources politics.

Key personal

We have a clear view of the expertise needed to execute the project. Hired personal will be splitted into three categories; direct labor , sales and administration and research & development.

Direct labor: During the first years, we will mainly hire laboratory technician with decent qualification to assembly the various piece that we will receive from our different suppliers. We are also looking to offer internship to university student in the field since the required work would be executable by them as long as they are supervised. The numbers of this type of employee and the amount of hour we will need them to work will be in function of our production needs and the growth of sales. Additional skills might be required in later stages where other types of tests will be developed.

Job position	Responsibilities	Competency	Type of contract	Estimated salary
Laboratory technician	Actively producing the products	Medium	Permanent/ Full-time	25\$ CAD /H
Senior laboratory technician	Actively producing the products while also supervising the activities	High	Permanent/ Full-time	35\$ CAD/H
Student Intern	Assisting technician in the production of goods.	Low	Seasonal/ temporary /Part-time	18\$ CAD/H
Cleaner	Cleaning the laboratory.	Medium	Permanent/ Part-type	20\$ CAD/H

Sales and administration: To ensure our presence at key marketing areas and increase the company visibility, we will need to hire skilled sellers. Also, since sales are an important part of the enterprise rentability, decent monitoring of those activities needs to be executed by a sales manager. Furthermore, various administrative roles need to be filled with experienced employee in the fields of finance, accounting, information technology, human resources, etc. Some of those skills will be acquired for a limited period of time through temporary contracts.

Job position	Responsibilities	Competency	Type of contract	Estimated salary (yearly)
Sellor	Promoting the product to our customers	High	Contractual	40'000\$
Business development director	Insuring compliance with call to tender offers	High	Permanent/ Full-time	60'000\$
Secretary	Taking call from various person and executing basic administrative tasks.	High	Permanent/ Full-time	40'000\$
Calling center representative	Will be important when the company will be bigger to be in contact with the different customer to guide them through the application	Medium	Part time	17'500\$
CPA (Chartered professional accountant)	General accounting controls, financial prevision, budgeting, etc.	High	Permanent /Part-time	70'000\$
Accounting technician	Executing accounting entries	Medium	Permanent/ Full-time	35'000\$
CTO (Chief Technology Officer)	Responsible of the information system and other technologie-related stuff.	High	Permanent/ Full-time	65'000\$
CHRP (Certified human resource advisor)	In charge of hiring the key personnel for every section of the company	High	Permanent/ Full-time	65'000\$

Research and development : Finding new ways of producing affordable tests providing reliable results is key to the long-term growth of the company. Investing in research enable the development of innovation ideas that could be monetized thereafter. It is therefore important to arm ourselves of the abilities of researchers in : Microfluidic, SPR, antibody detection fields, computer science and the help of advisory boards.

Job position	Responsibilities	Competency	Type of contract	Estimated salary
Microfluidic professional	R&D for future tests and technologies	High	Permanent	TBA
SPR professional	R&D for future tests and technologies	High	Permanent	TBA
Antibody detection professional	R&D for future tests and technologies	High	Permanent	TBA
Computer science	In charge of developing the softwares and other programming related work	High	Permanent	TBA
Advisory board : science	Validation of the concept by outside expertise.	High	Permanent	around 1% of the company
Advisory board : business	Validation of the concept by outside expertise.	High	Permanent	around 1% of the company

HR politics and methods

We are conscious that a having clear politics in terms of how work needs to be executed is important to ensure quality of the workplace and the products produced there. BiosensUM is seeking compliance with human resources standards throughout all it's activities. Following is a non exhaustive **list of various human resources politics** to implement.

Working hours

Open from 8 a.m. to 7 p.m., from Monday to Friday. Could be accessible during weekends if needed. We will pay overtime hours according to local legislations¹³.

Remuneration and social advantages

Salary will be determined on the position skill's requirements.

Social advantages will include health insurance such

Vacation plan

Vacation will scale up depending on the employee seniority. Every employee will have sick days and could miss work with a valid reason.

Employee training and improvement monitoring

One thing that is very important is to have a clear *formation plan* teaching new employees how to execute their work properly. It is especially true when it comes to technician because they are responsible of assembling the product that will be handed to our customers. The formation curriculum would include a set of distinct formations on specific technical subject, general information and procedures as well as the company code of ethics. The newly engaged worker will be able to access the information throughout his personal online portal.

Efficiency evaluation

Another aspect we will make sure to deploy is *continuous evaluation* of the work and providing feedback when needed. This task will be mainly done by managers whom will be evaluated by the direction. Those evaluations will help in making sure everyone his satisfying the criteria relative to his work task¹⁴.

¹³ Government of Canada., *Human resources regulations*. P.1

¹⁴ If you want more details about the various formation and evaluation, we will provide our employees with, please contact us at BiosensUM@gmail.com.

Financial viability

This section includes :

- A *company resume*
- The *operational costs*
- The *market size and market power*
- The *sales*
- The *revenues streams*
- The *statement of financial position*
- The *financial need*

The company

Commercial name	BiosensUM
Address	2900 Boulevard Edouard-Montpetit, Montréal, QC H3T 1J4
Phone number	1-514-917-5858
Email address	biosensum@gmail.com
Type of society	Private
Year of foundation	01-2018
Latest financial statements	N/A
Activity area	Medical

Operational costs

Cost of production

This sector will provide complementary information listing every single component needed to have an operational unit and microfluidic chips. The data will be presented as tables to which were added descriptions of the various assumptions leading to the establishment of every unitary cost of production and other expenses.

Device

Raw material*	Price	Quantity	Total
Polarizer	\$20,00	1	\$20,00
633 nm, f = 7.94 mm, NA = 0.50 SMA905 Fiber Collimation Pkg.	\$155,49	4	\$621,96
FC/PC Multimode Connector, Ø440 µm Bore, SS Ferrule	\$10,51	2	\$21,02
0.50 NA, Ø400 µm Core Multimode Fiber, High OH	\$2,39	0,2032	\$0,49
FC/PC Multimode Connector, Ø440 µm Bore, SS Ferrule	\$10,51	4	\$42,04
GT25-03 - Visible Transmission Grating, 300 Grooves/mm	\$112,41	1	\$112,41
Sub total			\$817,92
Workforce **	Wages	Hours	Total
Product assembly	\$30,00	0,25	\$7,50
Optical fiber	\$30,00	0,5	\$15,00
Sub total			\$7,50
Manufacturing Overhead***	Cost	Volume (unit)	total
Electricity	\$1 200,00	6000	\$0,20
Maintenance and repair	\$480,00	6000	\$0,08
Laboratory leasing****	\$0,00	6000	\$0,00
Laboratory insurances	\$600,00	6000	\$0,10
Director and officer insurance *****	\$10 000,00	6000	\$1,67
Other	\$600,00	6000	\$0,10
Sub total			\$2,15
Total cost of fabrication			\$827,56

Assumptions

* **Raw material:** A lot of the prices regarding raw material included in the cost of return are higher than they would have been if we were to buy larger quantities or produce them ourselves. Therefore, we expect the cost of production for these goods to decrease in price as we start finding better suppliers. In the long term, we will also invest in expertise to be able to produce the material ourselves as much as possible.

** **Workforce:** The raw cost is around 22\$/CAD per hour to which we add health insurance fees, workplace insurances and other legal expenses.

*** **Manufacturing Overhead:** Considering that we will sell more from a year to another, this price will certainly go down through the years. For example, we estimate our sells for the first year to be around 6 000 units while we predict the amount to increase to 19 620 the second year.

******Laboratory leasing:** For the first years, we were able to obtain a free lease in an incubator at Concordia university named District 3 (*see: <https://www.concordia.ca/research/d3center.html>*). This incubator provides us with all the basic equipment needed to execute the production. After those chargeless years, because this location is only available for start-ups, we would sign a lease at a cost of about 10\$ per square feet which bring us to an estimated 1000\$/CAD payment every month.

*******Director and officer insurance:** Basic protection against workplace injuries, pursuit and other legal actions that could be initiated against BiosensUM.

Microfluidic chips

Raw material	Price	Quantity	Total
Functionalization -peptide			
DMF (mL)	\$0,11	0,1	\$0,01
Ethanol (mL)	\$0,01	5	\$0,03
Unique usage plastic material	\$0,50	1	\$0,50
Peptide (mg)	\$1,50	0,1	\$0,15
Sub total			\$0,69
Functionalization - receiver			
Ethanolamine Hydrochloride (g)	\$0,60	3	0,045
TNF-alpha (µg/mL)**	\$0,05	50	\$2,55
Other products (NaOH/HCl)	\$0,05	1	\$0,05
PBS (ml)	\$239,00	0,0005	\$0,12
Prism	\$0,50	1	\$0,50
Sub total			\$3,26
Workforce***	Wages	Hours	Total
Washing the prism	\$30,00	0,014	\$0,43
Deposit of the chrome and gold	\$30,00	0,010	\$0,29
Functionalization with the peptide	\$30,00	0,005	\$0,14
Functionalization with the receptor	\$30,00	0,057	\$1,71
Sub total			\$2,58
Manufacturing Overhead	Cost	Volume	Total
Electricity	\$120,00	6000	\$0,02
Laboratory leasing	\$0,00	6000	\$0,00
Other*****	\$100,00	6000	\$0,02
Sub total			\$0,04
Total cost of fabrication			\$6,56

Assumptions

* **Raw material** : Here, once again, we expect the price of the raw material to decrease our volume of production increase.

** **TNF-alpha**: This cost includes everything it takes to produce the molecule during the year (the biochemist, the instruments and the raw materials: Purification kit for recombinant protein, PCR kit, SDS kit ...)

*** **Workforce**: The raw cost is around 22\$/CAD per hour to which we add health insurance fees, workplace insurances and other legal expenses.

**** **Other**: For example, office supplies, unexpected costs and other charge that could be linked to chip production.

Sales and administration expenses

Cost of sales	S1 2020	S2 2020	S1 2021	S2 2021	S1 2022	S2 2022
Publicity*	\$30 600	\$35 100	\$39 600	\$44 700	\$49 800	\$53 700
Salesman salary**	\$15 600	\$15 600	\$31 200	\$31 200	\$31 200	\$31 200
Expedition and delivery***	\$0	\$0	\$0	\$29 945	\$59 891	\$95 666
Amortization ****	\$0	\$0	\$0	\$0	\$0	\$0
Other	\$1 800	\$1 800	\$1 800	\$1 800	\$1 800	\$1 800
Subtotal	\$48 000	\$52 500	\$72 600	\$107 645	\$142 691	\$182 366
Administration costs	S1 2020	S2 2020	S1 2021	S2 2021	S1 2022	S2 2022
Research*	\$150 000	\$150 000	\$150 000	\$150 000	\$150 000	\$150 000
Salary (direction)**	\$30 000	\$30 000	\$30 000	\$30 000	\$120 000	\$120 000
Salary (employee)**	\$57 500	\$57 500	\$57 500	\$57 500	\$57 500	\$57 500
Professional fees	\$3 600	\$3 600	\$3 600	\$3 600	\$3 600	\$3 600
Telecommunications	\$480	\$480	\$528	\$528	\$600	\$600
Amortization	\$0	\$0	\$0	\$0	\$0	\$0
Office expenses	\$2 700	\$2 700	\$2 700	\$2 700	\$2 700	\$2 700
Insurance and taxes	\$0	\$0	\$0	\$0	\$0	\$0
Banking costs	\$156	\$156	\$156	\$156	\$156	\$156
Interest on LT debt	\$3 000	\$3 000	\$3 000	\$3 000	\$15 000	\$15 000
Patent***	\$0	\$1 500	\$0	\$3 000	\$0	\$400
Subtotal	\$247 436	\$247 436	\$247 484	\$247 484	\$259 556	\$259 556

Assumptions; cost of sales.

***Publicity:** Based on interviews with professional in the fields, we understood that the industry standard in term of publicity is around *10% of the previous year earnings*. Therefore, our forecast in terms of publicity cost took that information into account. Furthermore, we planned an increase in sales as more revenues will be generated in future years. Finally, we adjusted the amount to consider the inflation. (*for more details see section : Sales and marketing plan : Publicity*) .

****Salesman salary:** We are going to hire a part time salesman for the first year at the wage of 30\$ per hour (*include other fees*). To increase our sales, this position is going to be promoted as a full-time job for the second and third year.

*****Expedition and delivery :** The cost is estimated by applying an average price for shipping of 6\$ times the number of units sold.

******Amortization:** Since we are going to use the incubator's asset to produce our equipment, we won't be using any purchased assets that has a life duration long enough to require amortization. Note that later phase (*as stated in the action plan*) will require the purchasing of assets.

Assumptions; administrative costs.

***Research and development:**

****Salary (indirect) :** In the early phase, it will only include the salary of the seller, the accounting technician and the secretary as more experienced expertise would be required that early. . As of the salary of the direction, we would probably hire one person that has experience in the scientific domain as well as deepen management skills. (*for more details, see section: Human resources*)

*****Patent :** Before the beginning of this competition, we started the steps toward obtaining a patent in collaboration with the University of Montreal.

Market size and Market power

Market size

Year	1	2	3
# patient	378 259,00	388 623,80	399 272,61
Growth	-	0,0274	0,0274

Assumptions

***Growth :** We used a set of datas¹⁵ to find an average growth between years 2020 and 2025. We then divided that amount equally between five years which gave us the market size for Rheumatoid arthritis in Canada.

Table 5 Current and Future RA Prevalence by Sex, Canada, 2010 to 2040

Year	Men (% men total)	Women (% women total)	Total (% total population)
2010	82,085 (0.49%)	190,214 (1.11%)	272,299 (0.89%)
2015	97,985 (0.56%)	227,182 (1.27%)	325,168 (0.92%)
2020	113,813 (0.62%)	264,446 (1.43%)	378,259 (1.03%)
2025	129,245 (0.68%)	300,838 (1.57%)	430,083 (1.13%)
2030	143,438 (0.74%)	334,148 (1.70%)	477,586 (1.22%)
2035	155,433 (0.78%)	362,270 (1.79%)	517,703 (1.29%)
2040	164,815 (0.81%)	384,404 (1.87%)	549,218 (1.34%)

Market power

	Year 1		Year 2		Year 3	
Mkt parts %	0%	0%	0%	1%	3%	5%

Assumptions

Market parts (%) : The first two years, we won't be selling our product since it will in development. From then end of year two and the beginning of year three, we will focus on selling a single test throughout a limited set of distributors. By obtaining a contract with distributors, we plan on marginally increasing our sales until we reach a market power of around 15-20%. At that point we would sell various tests relative to RA and other illnesses.

¹⁵ Source http://www.arthritisalliance.ca/images/PDF/eng/Initiatives/20111022_2200_impact_of_arthritis.pdf

Sales- Device

Year	Y1 S1	Y1 S2	Y2 S1	Y2 S2	Y3 S1	Y3 S2
Sales	0	0	0	971,5595	4991	9982
% direct	0	0	0	291	1497	2995
%leases	0	0	0	680	3494	6987
year cum.	0,00		971		14 972	

Sales - Chips

Year	Y1 S1	Y1 S2	Y2 S1	Y2 S2	Y3 S1	Y3 S2
Sales	0	0	0	5 829	29 945	59 890

Sales

Based on the previous estimation of the market part, we took those numbers and multiplied them by the unitary price of every component we plan to sell when operational. All those transactions summed up gave the estimated sales for every period.

Year	S1 2020	S2 2020	S1 2021	S2 2021	S1 2022	S2 2022
Testors	\$0	\$0	\$0	\$4 022 239	\$20 662 266	\$41 324 532
Chips	\$0	\$0	\$0	\$406 475	\$2 129 827	\$4 344 847
Leases	\$0	\$0	\$0	\$216 472	\$1 134 260	\$2 313 891
Other	\$0	\$0	\$0	\$0	\$0	\$0
Total	\$0	\$0	\$0	\$4 645 186	\$23 926 353	\$47 983 270
Price testors*	\$4 140	\$4 140	\$4 140	\$4 140	\$4 140	\$4 140
Quantity sold	0	0	0	971	4991	9982
Quantity/year	0		971		14973	
Price chips**	\$66	\$67	\$68	\$70	\$71	\$73
Quantity sold	0	0	0	5 829	29 945	59 891
Leases earning***	\$300	\$306	\$312	\$318	\$325	\$331
Number of leases	0	0	0	680	3494	6987

Assumptions

In depth details for price determination are presented in the section : *price*. Here, we will simply show the analysis that led us into establishing a *referential unitary price* for each of our goods sold.

Cumulative economic burden of RA

(in billions)	2010	2015	2020	2030	2040
Total direct costs	2,4	16,1	31,5	62,2	94,6
Total indirect costs	3,3	22,2	45,1	100,1	162,8
Total economic burden	5,7	38,3	76,6	162,3	257,4

So, 76,6 billion dollars is the estimated economic burden for RA in Canada for the year 2020. While it is hard to estimate the amount of indirect cost our technology would help eliminate, we are confident that it would lower the time it takes for a patients to regain their usual lifestyle leading them into rejoining their everyday activities and participating in their community. Our hypothesis is that from the market part we have (15% at term¹⁶), our offering would *help solve 40% of indirect cost*.

(in billions)	2020	Costs tied up	Cost saved (15%)
Total direct costs	31,5	4,725	0,4725
Total indirect costs	45,1	2,706	0,1353
Total economic burden	76,6	7,431	0,61

Our device would help save \$7 431 000 000 thus \$4 725 000 000 in direct costs such as repetitive visit to the hospital and 2 706 000\$ in indirect cost such as invalidity. Obviously, our device won't help resolve all those costs, but we estimate that the advantages it provides such as time saving, and reliable results would lower these costs. The decrease would be **10%** for direct costs and **5%** for indirect costs. In conclusion, we could help save 610 000 000\$ by selling our product to 10% of patient .

¹⁶ See section : *Financial viability : Market size and market parts*.

Cost saved (35%)	0,61
# of patient helped	37826
Cost per patient	16068,36
Cost Gvn per patient (75%)	10444,43
Cost priv per patient (25%)	5623,92

After dividing the cost saved by the total number of patients helped, we obtain a cost per patient of \$16'068. That is how much could be saved per patient if our technology was adopted. Therefore, it is very advantageous for the government to allow substantial subsidy to help us reach our full potential, as it would save \$10444, per patient helped. Also, the part of the cost saved for the private sector is **\$5624** per patient which helps us into establish the unitary price for our products.

With the help of information acquired by interviewing André St-Amant¹⁷, a medical device distributor, we took note that prices in the field are around 4-6 times the cost of production for the device and 7-11 times for the chips. Based on that, our price for the device would be around 4000\$ and 66\$ for the chips. Finally, we adjusted the price to fit those standards as well as the cost it would save.

***Price device:** 4'140\$

****Price chips:** 66\$

*****Lease earnings:** For the lease, we estimated a utilization cost of 50 dollars per week (including the chips) which gave us a monthly amount.

S1	S2	S1	S2	S1	S2
\$299,94	\$305,94	\$312,06	\$318,30	\$324,66	\$331,16
			49,99	2%	

¹⁷ Andree

Financial Income Statement

This table provides information on the *gross profit* which is the margin we would be able to make on sales, the *BAI* representing the profit before deducting amortization, taxes and interests and finally the *net profit* which is the amount of pure income made during the period.

	2020	2021	2022
Sales	\$0	\$4 645 186	\$71 909 623
Cost of sales	\$0	\$1 408 209	\$21 722 979
Gross profit	\$0	\$3 236 977	\$50 186 644
Sale expenses*	\$100 500	\$150 300	\$169 500
Administration expenses	\$494 872	\$494 968	\$495 112
BAAII	-\$595 372	\$2 591 709	\$49 522 032
Public subsidy	150000	150000	400000
Amortization	0	0	0
Taxes (20,6%)**	0	\$533 892	\$10 201 539
Net profit	-\$595 372	\$2 057 817	\$39 320 494

*Sale expenses: The sales expenses the first year are due to spending on marketing and the hiring of a seller in order to generate sales in later phases.

**Taxes : Federal rate (9%) + Provincial rate (11,6%) = Total of 20,6%.

Here are a few explanations about the results shown on the table above. As you can see, the first year would lead to losses since we won't have any revenues. But during the next years our revenues would jump from 2 million to around 40M in third year. The idea is that after completing our research and obtaining the required certification we would start increasing our sales until we reach a total market power of 10-15%. At this stage, our projected revenues would be around 300-500M per year (assuming we maintain our margins and deals with key distributors).

Statement of financial position

This section provides an overview of the various assets, liabilities and equity BiosensUM would have throughout its expansion. Unfortunately, it is hard to estimate some element due to their nonexistence until the company really engage in commercial activities.

2020			
Assets		Liabilities	
Current assets		Current liabilities	
Cash balance*	N/A	Payables	N/A
Receivables	N/A	Interest on LTD	6000
Inventories	0		
Non-current assets		Non-current liabilities	
Plant	0	Long-term debt	100000
Property	0	Equity	
Equipment	0	Ordinary actions	N/A
Intangible assets**	800000	Retained earnings	0
2021			
Assets		Liabilities	
Current assets		Current liabilities	
Cash balance	N/A	Payables	N/A
Receivables	N/A	Interest on LTD	6000
Inventories	0		
Non-current assets		Non-current liabilities	
Plant	0	Long-term debt	100000
Property	0	Equity	
Equipment	0	Ordinary actions	N/A
Intangible assets	1600000	Retained earnings	\$533 892
2022			

Assets		Liabilities	
Current assets		Current liabilities	
Cash balance	N/A	Payables	N/A
Receivables	N/A	Interest on LTD	18000
Inventories	N/A		
Financial lease***	TBA	Non-current liabilities	
Non-current assets (estimated)		Long-term debt****	500000
Plant	600000		
Property	400000	Equity	
Equipment	20000	Ordinary actions	N/A
Intangible assets	2400000 0	Retained earnings	\$39 320 49 4

*When there is a N/A, it is because we can't really estimate those numbers without actually engaging in those activities. As soon as we start our operation, we will adjust the amount shown on those position to the actual value.

****Intangible assets:** It is hard to estimate the value of intangible assets before any sales have been made, however we capitalized all the cost we thought could be included as development fees. Estimation for years 2021 and 2022 are just a 100% increase from the basic amount incurred in 2020.

***** Financial lease:** Here again, it is hard to estimate the number a lease that will be considered as financial and not only contractual. Those estimations will be done after we start signing some leases.

******Long-term debt:** As planned in the section financial needs, we plan on increasing loans to finance our growth by adding an extra 400'000\$ loan to our liabilities.

Financial needs

This section briefly describes the assets we will need to acquire when we will leave the incubator. Much more details will be added when the acquisition time will be close. After leaving the incubator we will need:

-A plant

-A property

-Equipment : most of the equipment required will be used by our suppliers which lower the cost of this section. Most of the time, it is preferable to simply buy the material from them rather than producing it ourselves since they have a bigger volume of production then we do thus lower unitary costs.)

Example of equipment to acquire : Ultimaker S5 , a 3D printer which cost around 4'000\$.

-Working capital : Working capital is specially needed to make sure we are able to face our short-term obligations such as payments on the long-term debt, salaries and other punctual expenses.

-Research and development is our main financial need. We need to gather enough funds to carry out research and develop our products in the early stages. For that, we will proceed by obtaining a loan and as much subsidy as possible.

Contract 1	Date	2020
	Mortgagee	Bank-Desjardins
	Object	Loan
	Balance	\$100000
	Due date	janv.-2025
	Interest rate*	9%
	Reimbursement	9000
Contract 2	Date	2020
	Mortgagee	Government
	Object	Subsidy
	Balance	\$500'000
	Due date	N/A
	Interest rate	N/A
	Reimbursement	N/A

Contract 3	Date	2022
	Mortgagee	Bank-Desjardins
	Object	Loan
	Balance	400000
	Due date	janv.-2025
	Interest rate**	7,5%
	Reimbursement	36000

***Interest rate :** The interest rate is based on average loans for business which are ranging from 7,75% to 10%¹⁸.

Contract 1: The first loan we would sign is with Desjardins¹⁹, a Quebec bank which has great deals for small business. It is by far the best bank for funding since their policies are softer if our project were to need be financially viable (they don't sue individuals on their personal assets).

Contract 2 : There is a lot of subsidy available

- 1- : **PARI CNRC** - Programme d'aide à la recherche industrielle du Conseil national de recherches du Canada (<https://www.emergex.com/pari-programme-aide-recherche-industrielle/>)

This program provides financial support to eligible small and medium-sized Canadian companies that wish to develop technologies through direct grants that can reach \$ 500,000 (the average being \$ 94,000).

The program covers expenses on salaries (up to 80%) and subcontractors (up to 50%) related to the technological development of an eligible project, from the moment of signing the contract with the CNRC. However, it does not cover any upstream expenses (planning phase or before the signing of the contract) and after completion of the project phase of commercialization

- 2- **Alliance stratégique universitaire CRSNG** (http://www.nserc-crsng.gc.ca/Innovate-Innover/alliance-alliance/funding-financement_fra.asp#option1)

¹⁸FUNDERA., Business loans interest rate. P.1.

¹⁹ Desjardins. *Loan to small business*.

This subsidy can provide between \$ 150 000 to \$ 1 million per year to finance our R&D. Basically, the CRSNG will contribute X\$ per dollars invested for university employee to do research for our enterprise. It can be useful for us, if we want to develop new test in the future.

3- **Fonds de soutien à l'innovation en santé et en services sociaux**
(<https://www.economie.gouv.qc.ca/bibliotheques/programmes/aide-financiere/fonds-de-soutien-a-linnovation-en-sante-et-en-services-sociaux/>)

This subsidy makes it easier to obtain the data necessary for the commercial or operational implementation of innovations.

For this subsidy, the contribution of the Government of Quebec under the call for proposals cannot exceed \$ 250,000 per project, for a maximum duration of 24 months. Also, the financial assistance rate of the MESI cannot exceed 50% of eligible expenses.

Contract 3: After the first two years of research and development, we will aim to obtain more loans to make sure we have enough liquidity to maintain a working capital ratio above 1, and invest in assets such as a property and intangible assets created by R&D. We would probably keep on doing business with the same bank and negotiate our interest rate terms since there will be cash flows coming in.

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Annex

RA	2010	2015	2020	2030	2040 (\$ 2010)
Total direct costs	\$ 2.4 B	\$ 16.1B	\$ 31.5 B	\$ 62.2 B	\$ 94.6 B
Total indirect costs	\$ 3.3 B	\$ 22.2 B	\$ 45.1 B	\$ 100.1 B	\$ 162.8 B
Total economic burden	\$ 5.7 B	\$ 38.3 B	\$ 76.6 B	\$ 162.3 B	\$ 257.4 B

Cumulative cost for RA in Canada from 2010 to 2040

Source :

http://www.arthritisalliance.ca/images/PDF/eng/Initiatives/20111022_2200_impact_of_arthritis.pdf