

BUSINESS PLAN

Targo Consulting LTD.

Habonim 2

Ramat Gan, Israel

054-6861500

benitalanzer@gmail.com

Table of Contents

1	Executive Summary	4
2	Mission.....	5
3	Background.....	6
4	Products and Services.....	7
4.1	Features and Benefits	8
4.2	Product’s revisions.....	9
4.2.1	CT Product - revision 1	9
4.2.2	CT product - Revision 2 – commercial product.....	10
4.2.3	MRI product - Revisionrevision 1	11
4.2.4	Future products.....	11
4.3	Clinical.....	12
4.3.1	Proof of Concept.....	12
4.4	Development Plan	12
4.4.1	CT Product - first version.....	13
4.4.2	CT Product - Second version	14
4.4.3	MRI Product - First version	16
4.5	Intellectual Properties.....	18
4.6	Regulatory Strategy	18
4.7	SWOT Analysis	19
5	Economics	20
5.1	Market.....	20
5.1.1	Overview.....	20
5.1.2	Market Segmentation.....	21
5.1.3	Market Size	23
5.1.4	Market trends and barriers	25
5.1.5	Market penetration.....	26
5.2	Value proposition	28
5.3	Revenue Model / Business Model.....	29
5.3.1	ROI model.....	30
5.4	Competition	31
5.5	Mass Production.....	32

5.6	Sales Forecast	32
6	Management and Organization.....	32
7	Budget	33
7.1	First Year Budget	33
7.2	Next Two Year Budget.....	34

1 EXECUTIVE SUMMARY

Targo Medical develops a spine dedicated workstation that increases diagnosis rate of LBP from 30% to 70%. The diagnosis is based on quantitative analysis of the spine and its elements; measurements results of the spine and its elements are presented within a range of reference values based on statistical data collected from a large sample size of healthy population. By increasing diagnosis rate, Targo's system, enables physician to prescribe an accurate and effective course of treatment; allows NHS to create useful guidelines for better management of LBP; enables medical centers better allocation of funds; saves insurance companies the futile spending on unnecessary procedures.

LBP affects 80% of the population. There are guidelines and protocols on how to treat spine disorders, which not all physicians assent to. Radiologists often encounter inconsistency between symptoms, clinical findings and radiological picture, therefore, they cannot provide an accurate diagnosis. Lack of diagnosis prevents orthopedists to recommend treatment. In many cases clinicians depend on their subjective beliefs and agenda when they recommend a course of treatment. The outcome is high rate of unnecessary invasive procedure and ineffective physical therapy not addressing the source of pain. Both options, invasive and noninvasive treatments, have a 40% documented rate of pain reoccurrence. Current method of diagnosis is responsible for \$26B spending on treating LBP; a heavy burden on insurance companies and NHS.

Targo's concept is a breakthrough in diagnosis of LBP; measure not only the spine but also its elements; create a model of the spine based on general population segmented by gender, age and ethnicity cohorts; create a reference value scale; compare measurements numerically, schematically and graphically, thus enables Targo to provide an accurate diagnosis. Adoption and deployment of the new concept of quantitative analysis (similar to the one used in blood tests), will help to leap towards a new era, providing a solution to the LBP painful problem.

There are two million people in US and Europe that seek diagnosis and treatment. They account for only 10% of many others that suffer LBP. The imaging market is a growing segment in the diagnostic medicine and there 14M spine CT scans and 6M spine MRI procedures performed annually in the US & EU. In the US the price of spine CT is ~\$400 and the price of spine MRI is ~\$900 and in Europe the prices are the same but quoted in euros. The estimated profit of each procedure is 25%. There are two major changes in healthcare policy that create a business opportunity to Targo; accountable care organization (ACO) is a healthcare organization characterized by a payment and care delivery model that seeks to tie provider reimbursements to quality metrics and reductions in the total cost of care for an assigned population of patients; Obamacare or the Affordable Care Act (ACA) which some of its reforms suggests that CMS begins using the Medicare fee schedule to give larger payments to physicians who

provide high-quality care compared with cost. As changes take place and with the current growth in imaging market segment, Targo is looking at an annual TAM of \$350M.

Installing Targo's system is a "no brainer" as it easily interfaces within medical center IT systems; HIS, RIS and PACS. System's thin-client architecture ensures multiple users at the same time and enables radiologist to use its current monitor and practice using the familiar workflow, as well as volume rendering. Using Targo's system will not require any additional reading time per case, but will increase diagnosis accuracy.

Targo intends to deploy two optional revenue models; \$25K installation fee for capital equipment and additional \$10 fee per use; \$25 fee per use no installation fee. In both models company will gain additional revenues from a charge of \$500 annual fee for service and upgrades.

Targo's is seeking \$250K for seed funding to finalize first revision of product for research purposes. Seed proceeds will enable company to operate 1 year. Company is looking to raise \$2.5M in series A funding to finalize commercial product and its regulatory clearance.

2 MISSION

Targo's mission is to increase diagnosis of LBP, thus provide a solution to a widely prevalent disorder. Provide better diagnosis means provide better care to patient and facilitate management of LBP. One third of world population suffers from back pain, sometimes disabling. Due to current low diagnosis rate, management of LBP is challenging. Management of disorder has a predefined and clear protocol to guide physician on how to treat a patients' complaint; what are the screening procedures in order to diagnose the source of pain and what is the effective treatment to best solve the problem. Management effects all parties in healthcare; Patients, Medical Centers, Primary Care Physicians, NHS and insurance companies. Deploying Targo's nouvelle concept allows effective management of LBP for all to benefit from; better standard of care, better budget allocation, reduce spending on unnecessary procedures, increase in treatments (either invasive and noninvasive) volume with successful results.

The mission of Targo Medical Ltd. is to develop new patented quantitative spine analysis radiological system to enable accurate diagnosis of spine disorders. Targo's technology will significantly improve clinicians' ability to accurately diagnose Low Back Pain (LBP) , thus, enable management of LBP, resulting in better standard of care for patients. The new system will fill market niche that accounts for a minimum of \$1.2B in potential sales and additional reoccurring annual revenues of \$50M. By improving the accuracy of LBP diagnosis in medical imaging modalities (CT, MRI), Targo is expected to increase procedure volume and increase prospected reoccurring revenues. The product will be priced to appeal to a managed-care market that stresses

lowest cost of total diagnosis and treatment parameters. Price will present a quick ROI to end user and will reduce its expenses in the long run.

3 BACKGROUND

Low Back pain (LBP) is a widespread public problem, and is an increasingly prevalent disorder in the developed world. Back pain is cited as the second most common reason for family physician visits, affecting 80% of the population, responsible for most lost workdays and disability claims, and consequently has a significant socioeconomic impact¹. Musculoskeletal system diseases are the 6th most common reason for hospitalization in the US, with back surgery accounting for the most common inpatient. LBP consume more than \$90 billion annually in health-care expenses, with approximately \$26 billion of that amount directly attributable to treating the back pain. Frequently, diagnostic imaging procedure (CT or MRI) is performed following 3-6 month of continuing LBP. It is estimated that spine procedures account for 10-25% of all CT procedures in the US and Western Europe. Although extensive research has been made, merely 30% of chronic LBP patients have specific diagnosis (pain due to specific causes). Furthermore, no diagnosis indication for patients with non-specific LBP (no specific causes found) complicates considerably decision making regarding precocious steps (including surgery) and appropriate treatment. Moreover, often there is an inconsistency between the symptoms, clinical findings and the radiological pictures which intensifies the diagnosis problem. Due to inaccurate diagnosis, approximately 40% of patients undergoing lumbar surgery report significant pain following surgery.

Management of LBP is a challenging mission, especially when is the pain is persistent and disabling. There is no clear and agreed upon guideline to clinical practice, and low diagnosis rate of chronic LBP is the main reason. The diagnosis problem is rooted in clinicians' strong dependency on patients' unreliable subjective reported of pain, and lack of simple diagnosis tool for the wide variety of possible sources of pain. Studies estimate that only 30% of patient with Chronic LBP have specific diagnosis, but some also questioning the accuracy of current diagnosis. While many guidelines recommend to preform diagnostic imaging only when sever neurologic deficit appears and if patients are candidate for invasive treatment, due to lack of proper diagnosis method most clinicians refer 10-30% of the patients to CT or MRI. The adversity to identify the source of pain, even when diagnostic imaging is performed, impairs selection of an effective course of treatment, leaving clinicians empty handed.

The diagnosis problem of Chronic LBP makes it difficult to identify the source of pain and recommend an accurate effective treatment. Yet, there is an increase in lumbar surgical procedure rates. Many clinicians question treatment decision process since significant number of patients report reoccurrences of LBP following both noninvasive and interventional procedures. Furthermore, studies indicate that up to 10% of lumber

surgeries result in failed back surgery syndrome, due to improper screening, surgery selection, or diagnosis.

The acknowledgement of low rate of diagnosis and effectiveness of treatment affects patients' attitude towards course of action when experiencing LBP. It is estimated that only 60% of those experiencing back pain seek treatment, mainly due to severe and persistent pain, while the rest of the patients skip diagnosis and settle for home rest accompanied by pain relieve medications. Absenteeism due to LBP is directly related to reduced productivity, and its economic impact is considered as major factor in LBP cost estimations.

Management of LBP has a significant influence on its direct and indirect economic expenditure. Proper management allows Medical centers and NHS better allocation of budgets and incorporating various interdisciplinary treatment methods. Currently, low rate of diagnosis impedes effective treatment and adversely impacts health system and patients' quality of life. Methods increasing LBP diagnosis rate and accuracy will enable to substantiate a clear and comprehensive guideline, prevent futile procedures, reduce costs and enable management of practice.

4 PRODUCTS AND SERVICES

Targo's product enables LBP diagnosis. In its fresh and pioneering outlook at LBP and other spine disorders such as scoliosis, kyphosis, spondylolithesis, spinal stenosis, etc., Targo's technology applies quantitative evaluation of the spine versus the qualitative method that is currently deployed in spine imaging diagnosis. This new approach facilitates a significant increase in diagnosis rate and effective management of LBP.

Targo's system is a spine dedicated workstation to enhance diagnosis of LBP. The original concept of analysis method to evaluate cause of LBP is based on comparing quantitative characteristics of the examined spine to a statistical model derived from individuals with no spine problem. The model is reference based and it derives from a large sample size statistical research conducted on healthy population.

Utilizing this quantitative analysis method enables radiologist to identify and characterize the source of pain. Moreover, this analysis method provides a reliable correlation between the morphological picture to patient complaint, thus, enabling the physician to provide an accurate diagnosis.

Our system automatically extracts quantitative characteristics of the spine and its morphological components, structure and features. The quantitative results are presented alongside the reference values based on the normal range of the general population segmented by gender and age cohorts. The system enables radiologist to provide a comprehensive and more accurate diagnosis, allowing orthopedist to define an effective course of treatment, thus improve standard of care, prevent amiss

treatment and save costs of reoccurring illness. By increasing diagnosis rate, better management of LBP is attainable, benefiting all parties involved; medical centers, insurance companies, private practitioners and patients.

Our system automatically identifies various elements of the spine such as spinal canal, intervertebral disks, ligaments and muscles. Subsequently, system calculates elements' morphological characteristics, such as spinal canal area, disk height, muscle fat content, etc. The radiologist can simply compare the values provided by our system to the statistical model in the system and determine deviation from norm. The comparison will not require more than one click and will not prolong his review time. Our application enables a quick and efficient review and analysis of spine scans as well as volume rendering. It has a simple, seamless and intuitive workflow. Images can be also stored directly on a potable memory device such as CD and/or Memory stick, in a friendly format to be viewed by patient and/or other physician.

Targo system is integrated within "of the shelf" server, based on a thin-client server architecture. This structure allows an easy installation and convenient deployment of our system within the center. The system fully interfaces with centers' PACS and RIS, allowing radiologist to retract any new spine study and review it anywhere and anytime.

4.1 FEATURES AND BENEFITS

Addressing workflow issues has become of utmost importance in the CT industry, considering the amounts of image data and the larger user groups involved in the diagnosis process. One aspect is the reading workflow, and offering radiologists maximum flexibility in their work. In recent years, PACS systems have materialized the concept "images anywhere, anytime", allowing for image distribution throughout the enterprise and beyond. Further improvements using thin-clients and smart-clients have allowed to distribute not only the image viewing functionality, but PACS' clinical tools as well. In practice, this means that all the PACS tools are made available to referring physicians, and radiologists can now work remotely. This capability is instrumental in responding to the shortage of radiologists affecting North American providers. Traditionally, CT scanners are connected to a dedicated workstation, usually in the reading room, that contains all the clinical application software. For the growing majority of radiologists using PACS, this model implies that they have to move back and forth between the CT workstation and the PACS workstation. 3-D and advanced visualization software are increasingly deployed as thin clients and integrated with PACS. An emerging trend is to use thin-clients to make the CT application software available from any access point, and potentially incorporating them within the PACS interface. This way, clinical applications become available to radiologists from any location, and referring physicians are empowered with more tools. Such technology can constitute an important workflow multiplier.

4.2 PRODUCT'S REVISIONS

4.2.1 CT PRODUCT - REVISION 1

Company's first product is a spine CT analysis workstation. The first revision of the product is primarily a major step in the company's regulatory strategy and is not intended for commercial use or for sale. This product will be deployed as a clinical research platform, to assess workflow and user experience, to test setup and connectivity within imaging centers' system, etc. Targo intends to file for 510(k) clearance on the first revision, based on an existing commercial predicate. Therefore, the features and definitions of the product will be similar to those of potential predicates available in the market with and addition of several quantitative calculations with reference values. The values that will be presented in product's 1st revision will be based on published literature. We also intend to integrate few workflow improvements based on radiologists experience with current radiological workstations and PACS viewers. Targo intends to use this product as a predicate to its future commercial revisions when filing for FDA clearance.

The first revision of our product will be used to verify full integration of our device within Medical Center's workflow and prove its compatibility to HIS, RIS and PACS. At the end of the development and QA, product will be installed in two Alpha sites during that stage; Targo will explore which features are required by end user and clients (Radiologists, Orthopedists, patients).

4.2.1.1 FEATURES

The first revision of the Targo's workstation will be based on a features and capabilities of standard commercially available general CT viewers; common viewing options, main image manipulation tools and measurement tools. Viewing options will include: tiled view of axial coronal and sagittal planes Multi-Planar Reformatting (MPR), maximum intensity projection (MIP), volume rendering.

Main image manipulation tools will include: window/level, zoom/pan, toggle overlay/ annotations, flip/rotate, etc.

Common measurement tools will include: Elliptical / Rectangle / Polygon ROI with area, mean and STD calculations, line / curve length, 2D / 3D angle, Pixel or Point tool, etc.

In addition to the features and capabilities described above revision the workstation will include the following improvements:

- The user interface design will target spine studies, yet, intuitive and with minimum user clicks

- The algorithm will automatically identify and present spinal canal centerline and vertebrae bodies
- The quantitative measurements will include Cobb angle calculation for lordosis, vertebrae height and beveling, disk height.
- All quantitative measurements will be presented with reference value (in the initial stage just as an additional information)

4.2.1.2 HARDWARE

First revision of product will be an “of the shelf” server or workstation such as HP Z220, or Dell Precision, with Intel i7 / Xeon processor 32GB RAM, etc. Estimated price of this hardware configuration is \$2000.

4.2.2 CT PRODUCT - REVISION 2 – COMMERCIAL PRODUCT

Targo’s product revision 2 will be a commercial revision intended for sale. The system will be a medical imaging application for analysis of the spine and its elements to allow accurate LBP diagnosis. This revision will include a wide range of quantitative analysis tools, which will enable radiologist to give an accurate diagnosis. Some of the product’s capabilities will be based on 1st revision features. The product will be based on a thin-client architecture. All measurements and UX improvements will be based on research, clinical studies and alpha sites feedback.

4.2.2.1 FEATURES

- The product will be based on a thin-client architecture that will allow radiologist to use any PC as diagnosis station, thus, deploy the existing system and reduce IT administration and management. Moreover, it allows easier management of Pay-Per-Use bundle.
- Workload supports up to 15 concurrent clients (upgradable)
- System will enable automatic processing so diagnosis does not exceed current time frame of diagnosis, although providing additional features. Automated tasks will ensure that radiologist performs according to its predefined quota without compromising the quality of diagnosis but even perfecting it significantly, with better UX.
- System will automatically identify the spine elements and extract different characteristics of the spine and its morphological components, structure and features.
- Quantitative measurements include characteristics of the following elements: vertebrae disk, spinal canal and muscles.
- The system will present the quantitative results alongside reference values based on the normal range of the general population segmented by gender and age cohorts, together with visual illustration of the results.

4.2.2.2 HARDWARE

The commercial revision of product will be integrated within an “of the shelf” server such as Dell R620, or HP ProLiant DL360, dual CPU (2x Intel Xeon E5-2670), 32GB RAM (8x4GB DDR3-1600 ECC-Registered), with sufficient storage for scans few days back, windows Server 2008 64bit, etc. The hardware configuration can support up to 15 concurrent clients and the estimated price of this server is \$10000.

4.2.3 MRI PRODUCT - REVISION 1

Targo’s commercial system MRI application will be a medical imaging application for analysis of the spine and its elements to allow accurate LBP diagnosis based on MRI scan of the spine. The application will be similar to the CT application and will include a wide range of quantitative analysis tools, which will enable radiologist to give an accurate diagnosis. Similar to the CT product, it will be based on a thin-client architecture and include several measurements and dedicated UX.

4.2.3.1 PRODUCT FEATURES

- The product will be based on a thin-client architecture that will allow radiologist to use any PC as diagnosis station, thus, deploy the existing system and reduce IT administration and management. Moreover, it allows easier management of Pay-Per-Use bundle.
 - Workload supports up to 15 concurrent clients (upgradable)
 - System will enable automatic processing so diagnosis does not exceed current time frame of diagnosis, although providing additional features. Automated tasks will ensure that radiologist performs according to its predefined quota without compromising the quality of diagnosis but even perfecting it significantly, with better UX.
 - System will automatically identify the spine elements and extract different characteristics of the spine and its morphological components, structure and features.
 - Quantitative measurements include characteristics of the following elements: vertebrae disk, spinal canal and muscles.
 - The system will present the quantitative results alongside reference values based on the normal range of the general population segmented by gender and age cohorts, together with visual illustration of the results.

4.2.3.2 HARDWARE

The commercial revision of product will be integrated within an “of the shelf” server such as Dell R620, or HP ProLiant DL360, dual CPU (2x Intel Xeon E5-2670), 32GB RAM (8x4GB DDR3-1600 ECC-Registered), with sufficient storage for scans few days back, windows Server 2008 64bit, etc. The described hardware configuration can support up to 15 concurrent clients and the estimated price of this server is \$10000.

4.2.4 FUTURE PRODUCTS

Targo intends to continue its development revision in several courses; additional CT and MRI spine analysis for LBP diagnosis product revisions; other imaging analysis products (e.g. other spine disorders, screening tools); small spine analysis product for use in orthopedic clinic setup.

4.3 CLINICAL

4.3.1 PROOF OF CONCEPT

Founders conducted a scientific research that proposed a new automated method to obtain an accurate 3-D graphical spine curvature, parallel to numerical data that detects its deviations from the norm at any given point along its length. The method is based on CT imaging, and relies on two novel concepts: the spine curvature derives from spinal canal centerline, and evaluation of the curve is carried out against a statistical model of healthy individuals. The research included large clinical data based on more than 250 individuals. Two additional feasibility studies were performed on smaller sample of participants in order to attest to certain aspects of the method.

The occurrence of higher rate of curve deformation among individuals with non-specific LBP (32.1%) suggests that there is a clear correlation between spinal curvature deformation and LBP in many individuals. Validation results clearly show that the proposed method is suitable for detection and quantification of curve pathologies.

The main study demonstrated the advantages of Targo's analysis method to improve our understanding of the association between spine curve geometry and LBP. Targo's model enables clinicians to give a quantitative evaluation of the spinal and the location and severity of the deformation. The analysis also provides the exact the location and exact type of the deviation (e.g.: hyper-lordosis, mild scoliosis).

In the two small feasibility studies examining several unique muscle characteristics we have shown that muscles characteristics of individuals with LBP are different from those of individuals without LBP. This suggests that muscles physiology may have a key role in LBP development. We believe that our method of muscle assessment can contribute to the efficacy of our method of LBP diagnosis, thus, allocate an accurate treatment and increase its effectiveness.

4.4 DEVELOPMENT PLAN

In order to complete its full featured workstation that includes CT and MRI analysis, Targo plans to engage in R&D for a course of 30 months. During that time we plan two key product releases for the CT application and two key product releases for MRI application. Further down its R&D roadmap, Targo intends to release additional spine diagnostic applications as well as a spine diagnostic device designed for orthopedics' practice. The latter will assist orthopedists to define an effective course of treatment, without the use of CT or MRI.

Targo Medical image analysis product line includes CT and MRI workstation that facilitates quantitative analysis of the spine. The initial product is a CT application that will perform quantitative analysis of the Spine to support diagnosis of LBP and other spine disorders. Targo plans to have two key product releases of the CT application in a course of 30 months. Targo's next product will be MRI application similar to the CT application. Further down the roadmap, Targo also intends to develop an additional spine diagnosis applications as well as a dedicated device for spine diagnosis designed for orthopedics' practice in order to assist with defining an effective course of treatment, without the use of CT or MRI.

4.4.1 CT PRODUCT - FIRST VERSION

The first version of the CT analysis workstation will include a medical imaging viewer and a small set of quantitative analysis tools.

Software: design and development of medical imaging workstation based on commercially available library, including several screens, workflow, results report, and connectivity (connectivity to HIS, RIS, DICOM, etc.). The results screen will include visual presentation of quantitative results alongside reference values, together with visual illustration of the results.

Algorithms: implementation of several automated algorithms including: spinal canal centerline extraction, vertebrae identification, vertebrae bodies' identification. The quantitative measurements included wide range of element characteristics.

4.4.1.1 TIME TABLE

We expect to conclude the development of this version within 4-6 months. Following the completion of the development, the next steps will be quality assurance and clinical validation, which are expected to be completed within 1-2 months. Upon completion of QA and V&V, Targo will commence its alpha stage in 1-2 sites, and will file FDA submission.

ID	Project	Task Name	2013		2014	
			Q3	Q4	Q1	Q2
1	CT product rev 1					
2		Development				
3		Clinical				
4		QA				
5		V&V				
6		FDA				

4.4.1.2 PERSONNEL

In order to meet its projected tasks, this version requires 3 work months of algorithm development, 3 work months of software development, 1 work months of software tester for QA, and 1-2 work months of clinical application specialist (for product specific clinical validation).

4.4.1.3 RESOURCES

Product framework will be based on a commercial medical imaging infrastructure strategy that includes viewing capabilities (e.g. volume rendering), DICOM support, and algorithmic infrastructure (Claron Technology Inc., Canada) and on our nouvelle algorithms, identifying spine and its partitioning, canal segmentation, etc.

The development will be carried out using Microsoft Visual Studio, we expect to receive through Microsoft partnership program.

4.4.1.4 BUDGET

Personnel		Costs	Remarks
Dev	SW / Alg	\$40K	
	QA	\$6k	Med Dev
Clinical	Clinical Validation	\$18K	
Equipment			
Dev	SW libs	\$36K	Clron Tech
	Dev Computer	\$5K	
Clinical	Alpha Site Computer	\$5K	
Total		\$110K	

4.4.2 CT PRODUCT - SECOND VERSION

As describe above the second version of the CT product will include a wide collection of quantitative analysis tools, be based on thin-client architecture, and have additional measurements and UX improvements, following further development, clinical studies and alpha sites feedback.

Software: design and development of medical imaging server and thin client viewer based on commercially available library. The development includes thin client, application screens and workflow, results report, and server connectivity (connectivity to HIS, RIS, DICOM, etc.). The results screen will include visual presentation of quantitative results alongside reference values, together with visual illustration of the results.

It could also include development of a small portable viewer for the referring physician, with simple dicom viewer and dedicated viewer to present the results visually.

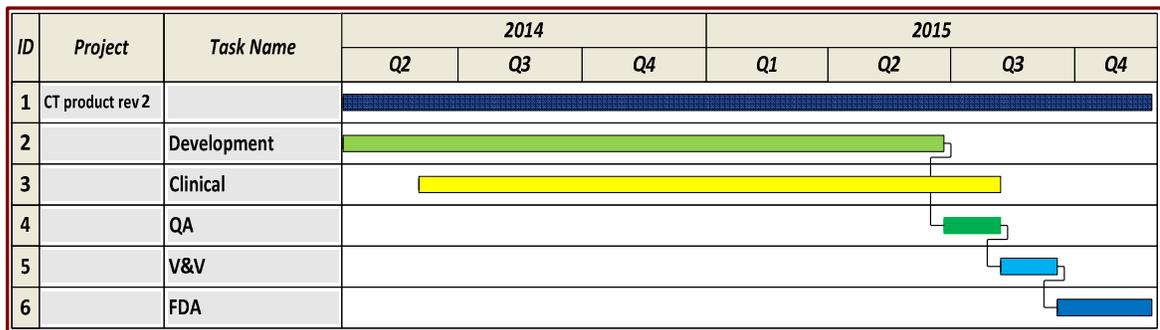
Algorithms: this version will have several automated algorithms including: centerline canal extraction, vertebrae identification, vertebrae bodies' identification, discs

segmentation, spinal canal segmentation, spinal cord segmentation, muscles identification, muscles segmentation (2D). The quantitative measurements included wide range of element characteristics.

Clinical: define clinical studies, define clinical studies, collect clinical data, etc.

4.4.2.1 TIME TABLE

We expect to conclude the development of this version within 12-15 months. Following the completion of the development, the next steps will be quality assurance and clinical validation, which are expected to be completed within 1-3 months. Upon completion of QA and V&V, Targo will commence its beta stage starting with 1-2 sites from 1st version up to 10 beta sites within 18 months, and will file FDA submission.



4.4.2.2 PERSONNEL

In order to meet its projected tasks, this version requires 36 work months of algorithm development, 6 work months of software development, 6 work months of software tester for QA, and 6 work months of clinical application specialist (for product specific clinical validation).

4.4.2.3 RESOURCES

Product framework will be based on a commercial medical imaging infrastructure strategy that includes viewing capabilities (e.g. volume rendering), DICOM support, and algorithmic infrastructure (Claron Technology Inc., Canada) and on our nouvelle algorithms, identifying spine and its partitioning, canal segmentation, etc.

The development will be carried out using Microsoft Visual Studio, we expect to receive through Microsoft partnership program.

Hardware: the development requires 5 development computers and 3 servers. We are planning to have 10 Alpha sites each requires a server.

4.4.2.4 BUDGET

Personnel	Per Month / No. of Months	Costs	Remarks

Dev	Project Management	\$13K/ 9	\$120K	
	Algorithm Development	\$8.5-13K/ 36	\$360K	
	SW	\$8.5K / 6	\$48K	
	QA	\$3K / 6	\$18K	
Clinical	Clinical Validation	\$15K / 6	\$90K	
Resources				
Dev	SW libs	\$6K / 15	\$90K	Claron Infrastructure
	Dev Computer	5x \$3K	\$15K	
Clinical	Servers	3x\$10K	\$30K	
	Alpha Site Computer	10x \$10K	\$100K	
Total				

4.4.3 MRI PRODUCT - FIRST VERSION

The MRI analysis product, similar to the CT product, will include a wide collection of quantitative analysis tools, be based on thin-client architecture.

Software: adaptation to MRI of the application screens and workflow, results report, and server connectivity. The results screen adapted to MRI data results will include visual presentation of quantitative results alongside reference values, together with visual illustration of the results.

Algorithms: this version will have several automated algorithms for MRI data including: centerline canal extraction, vertebrae identification, discs segmentation, spinal canal segmentation, spinal cord segmentation, muscles identification, muscles segmentation (2D). The quantitative measurements included wide range of element characteristics.

Clinical: define clinical studies, define clinical studies, collect clinical data, etc.

4.4.3.1 TIME TABLE

We expect to conclude the development of this version within 10-12 months.

Following the completion of the development, the next steps will be quality assurance and clinical validation, which are expected to be completed within 1-3 months. Upon completion of QA and V&V, Targo will commence its alpha stage in 1-2 sites, and will file FDA submission.

ID	Project	Task Name	2015		2016		
			Q3	Q4	Q1	Q2	Q3
1	MRI product rev 1						
2		Development					
3		Clinical					
4		QA					
5		V&V					
6		FDA					

4.4.3.2 PERSONNEL

In order to meet its projected tasks, this version requires 24 work months of algorithm development, 6 work months of software development, 6 work months of software tester for QA, and 6 work months of clinical application specialist (for product specific clinical validation).

4.4.3.3 RESOURCES

Product framework will be based on a commercial medical imaging infrastructure strategy that includes viewing capabilities (e.g. volume rendering), DICOM support, and algorithmic infrastructure (Claron Technology Inc., Canada) and on our nouvelle algorithms, identifying spine and its partitioning, canal segmentation, etc.

The development will be carried out using Microsoft Visual Studio, we expect to receive through Microsoft partnership program.

Hardware: the development requires 5 development computers and 3 servers. We are planning to have 10 Alpha sites each requires a server.

4.4.3.4 BUDGET

Personnel		Timeline	Costs	Remarks
Dev	Project Management	\$13K/ 6	\$78K	
	Algorithm Development	\$8.5-13K/ 24	\$240K	
	SW	\$8.5K / 6	\$48K	
	QA	\$3K / 6	\$18K	
Clinical	Clinical Validation	\$15K / 6	\$90K	
Resources				
Dev	SW libs	\$6K / 15	\$90K	Claron
	Dev Computer	5x \$3K	(\$15K)	(from prev dev phase)
Clinical	Servers	3x\$10K	(\$30K)	(from prev dev phase)
	Alpha Site Computer	10x \$10K	(\$100K)	(from prev dev phase)

4.5 INTELLECTUAL PROPERTIES

Company's IP attorney office is Webb & Co. based in Rehovot Industrial zone, Israel.

Targo medical Ltd. is currently focused on development of software to support diagnostic interpretation and evaluation of spinal imaging examinations. The intellectual property program and strategy reflects and support company's business focus, yet, is robust enough to support optional re-directions without becoming inefficient or cumbersome in operation. The ongoing tactics and operation of the patent program is considered along with development strategy in light of the resources (people, training, time and money) that management plans to commit. The issues that company faces when developing corporate patent programs include among others; technology innovator vs. fast-follower, standards developer vs. standards adopter, broad vs. niche market(s), focus on revenue vs. profit protection, geographic markets, etc. Company's IP strategy also includes assessment of competitors, intended (1-3 year and long-term) future market trends and directions, and level of risk aversion for various potential business situations. Targo Medical Ltd. is the owner (assignee) of the patents which are designed to stop others from making, using, selling and importing articles that infringe the claims of the issued patent. While each country's laws are different, Targo has focused its portfolio in the USA where substantial markets and litigation occur.

Company has filed one patent application - "Assessment of Spinal Anatomy" (WO2011021181). Patent is protecting Targo's core technology of modeling the spine and/or parts based on extraction of anatomical and/or morphological features or elements of the spine from imaging modalities, and consequently constructing a model of the spine or its parts. In a preliminary patent search that was conducted by patent office and its affiliates, no conflicting patents were found. Targo intends to file four additional new patent applications within its first year.

4.6 REGULATORY STRATEGY

Company regulatory attorney is Dr. John Smith of Hogan Lovells based on Pennsylvania Av., Washington DC, US.

Targo's regulatory strategy is to seek FDA compliance on its first CT analysis revision based on a full compatibility to a PACS predicate. We consider Syngo by Siemens, Vue by Carestream, Vitrea by Vital images as potential predicate. Our system will have a similar indication of use and intended use. By doing so, company is expected to have a short and straightforward regulatory pathway, avoiding any prospective clinical studies. Estimated period for regulatory clearance is 120 days including preparation for submission. In order to have maximum efficacy, company will adapt its method of operation to practice all research and development to comply with regulatory requirements: version traceability, design documents, validation and verification.

Achieving ISO & CE compliance is expected during the first year. The estimated cost of regulatory clearance is \$20K-\$30K.

Targo intends to use FDA 510K clearance on its first product as a predicate for the second revision of its CT analysis application that will be a commercial version. In order to mitigate risks and unknown impediments, Targo will submit request for Pre-IDE, in order to fully understand and prepare to agency's requirements. The commercial product is expected a 510K class 2. Labeling of intended use of the product will be as clinician decision support product. Following agency's response Targo will design its clinical study and full feature list. The estimated cost of regulatory clearance is expected to be \$50K-\$70K.

Similarly Targo intends to use the same strategy to receive FDA 510K clearance for its MRI analysis product. Targo intend to continue its development to include additional applications such analysis for other spine disorder. Company will follow development with regulatory pathway, though requirements and estimated cost are yet, ambiguous.

4.7 SWOT ANALYSIS

<p>S</p> <p>Strengths</p> <ul style="list-style-type: none"> • Offer better LPB diagnosis • Enable real management of LBP • Allow effective treatment • Improve standard of care • Fully automated calculations • Cost saving by reducing FBSS 	<p>W</p> <p>Weaknesses</p> <ul style="list-style-type: none"> • ROI is somewhat complex • Require large scale clinical trials for spine model and reference values • New distribution model with Pay-Per-Use model
<p>O</p> <p>Opportunities</p> <ul style="list-style-type: none"> • Large LBP market • Insurance Companies save money due to better management of LBP • Reimbursement change to pay per capita (instead of service) • Obama care Act • Cost saving due to ACO 	<p>T</p> <p>Threats</p> <ul style="list-style-type: none"> • Dedicated product limits fallback position and future application • Imaging market is very competitive • Poor validation results in clinical trials

5 ECONOMICS

5.1 MARKET

5.1.1 OVERVIEW

Targo's product is enabling diagnosis of LBP, therefore it address a highly segmented market in terms of stakeholders, beneficiaries, trends and methods of practice. Low back pain management involves several different clinicians expertise and practices. Diagnosis is usually carried out by primary care physicians, orthopedists, or pain doctors, further diagnosis includes medical imaging (radiology), EMG, Treatment of mild LBP is carried out by primary care physicians or orthopedists, while chronic LBP is usually addressed by orthopedists, as well as physical therapists and chiropractors for non-invasive treatment and orthopedists, interventional radiologists, neurologists when minimally invasive or surgery is advised. The diagnosis and treatment can be carried out by private practices and medical imaging centers, or large health facilities and hospitals offering wide range of clinicians.

Although there are guidelines for diagnosis and treatment of LBP, those guidelines are not agreed upon, leading to ineffective management and low standard of care and ultimately, many patients suffering from long lasting or reoccurring disorder. Patients suffering of LBP either turn to their primary care physicians, orthopedist or pain doctors, which usually prescribe pain-killers, while maintaining home activity, and/or refers to physical therapy. In cases of severe, disabling, or long lasting pain, clinician may refers patient to further tests, mainly diagnostic imaging procedure either CT or MRI. Many primary care clinics also own imaging equipment (including CT and even MRI), so there is incentive for imaging referrals.

When patients suffering of LBP initially turn to their primary care physicians, they and/or refers to physical therapy. or pain projection to other body parts and or acute disability or pain continues for more than three month, clinician refers patient to a diagnostic imaging procedure either CT or MRI. Many of the primary care physician clinics are owners of imaging equipment, so there is high incentive for imaging referrals. Currently imaging analysis is mostly qualitative and has a low rate of diagnosis and large inconsistency between the diagnosing and the source of pain. Currently only 30% of patient with chronic back pain have specific diagnosis, even with imaging, making LBP management challenging. Often there is low correlation between the patient complaint, the anatomical picture, and the actual pain source, frequently leading to low efficacy of treatment, and reoccurring LBP, for both invasive or noninvasive procedures. Furthermore, a common complication following surgery is Failed Back Syndrome (FBS), known to be costly and challenging.

The role of medical imaging in the diagnosis of LBP is still debated, as discussed by numerous articles published on this concerning issue, suggesting contradicting conclusions; lumber spine imaging increases patient's risk and the imaging procedures

improve patient care. Both conclusions are right; if diagnosis rate is low, there is no point in performing lumbar spine scan, but by increasing diagnosis rate, imaging becomes fundamental.

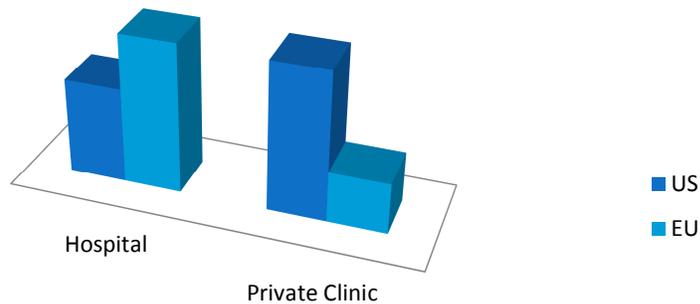
Another major concern in management of LBP is the new Obama-Care act (PPACA) and its effect on the reimbursement policies of insurance companies. Although details are not fully seen, it is clear that the rules of the game will change and what used to be profitable may be an economic burden. With improving patient care as one of its main goals, PPACA may be the best promoter of Targo's product.

5.1.2 MARKET SEGMENTATION

The LBP market includes diverse segments, sometimes with contradicting concerns and practices. LBP management - diagnosis and treatment process – involves several types of clinicians in terms of expertise (e.g. primary care physicians, orthopedists, physical therapists, etc.), institutions (e.g. private clinics, hospitals, public health program, insurance companies, etc.) and practices (e.g. patient centered. invasive/non-invasive treatment, etc.). Targo's immediate target markets are medical imaging centers and departments, such as private imaging centers with no affiliations, imaging centers part of larger private healthcare providers, or radiology departments in hospitals, having different (sometimes contradicting) concerns, appeals, and practices, suggesting different attitude toward change in practice guidelines and adoption of new technologies. Targo incorporates multiple considerations when building its business case based of the diverse LBP market segments. There are sometimes contradicting concerns, appeals and consequences to each of the participating segments following a change in practice guidelines and adoption of new technologies. An additional factor that influences company's business strategy is the geographic segmentation of the target markets; US market versus the European market present different guidelines, considerations and barriers towards adopting new method of practice and new technologies. In this section we will reflect only the western market analysis, the Asian market and the Central American market is pending further investigation.

Private market Versus Public sector – In both US and Europe the public sector is a major key player in the healthcare market. Although the public sector has major budget constraints, heavy regulation, government supervision, and bureaucratic management, it has the largest market share (in terms of patient's admissions and expenditure) and a significant impact on method of practice. But the growth in demand for private healthcare practices that started in US and is slowly shifting to Europe and its increasing market share, needs to be taken in consideration when planning market penetration.

Market Share by Institute



	Hospital	Private Clinic
US	6,000	9,400
EU	9,500	3,200

Private imaging in the US is rapidly growing segment; Since 2005, ownership or leasing of MRI equipment by non-radiologists grew by 254%, while MRI equipment owned by radiologists only grew by 83%. According to the US Government Accountability Office, the proportion of non-radiologists billing for in-office imaging more than doubled from 2000 to 2006. During that same time period, private office imaging rates by non-radiologists who control patient referral grew by 71%. Physicians who own their imaging equipment are more likely to refer their patients for imaging exams.

Primary care physicians (and radiologists) will be able to provide better practice, when utilizing Targo's system. Early and accurate diagnosis of LBP specific source of pain will enable practitioners to offer effective course of treatment and refer patient to the right specialist. The significant increase in imaging diagnostics procedure volume will be justified as it is improving patient care contradicting claims of exposure to additional dose of radiation in CT.

Significant share of the patients with chronic LBP are referred to orthopedists and undergo surgeries due to absence of accurate diagnosis. Medical centers and orthopedists benefit from a high rate of back surgeries as it is a profitable procedure. But research has shown that the rate of reoccurring pain is 40% and the rate of FSB is as high as 10%.

Insurance companies, play a major role in the dynamics of the LBP market. Recently, there have been a change in policy and medical centers are expected to provide care for patients and be accountable for the quality, cost, and outcomes. ACO - Accountable Care Organizations leads a change in reimbursement structure; compensation moves from fee-for-service to a per-capita fee. Doctors will need to make sure they are

ordering the appropriate tests, ensure radiology services meet the needs of the referring physicians, and that they provide good, consistent results, clear follow-up recommendations.

5.1.3 MARKET SIZE

In order to have an educated estimate of the total size of its target market, Targo preformed a market analysis; first step was segmenting the market than analyzing the effect of each segment on Targo's product TAM (Total Addressable Market). Market segmentation includes two main segments that directly affect Targo's market; number of patients suffering LBP and number of referrals to diagnostic imaging procedure. Additional segments such as; number of patients attending a physician, number of primary care clinics, success rate of various LBP treatments (invasive, minimally invasive and noninvasive) and number of lumber surgeries performed have a secondary influence on Targo's ability to present its business case and offer an attractive ROI to end user.

IMAGING PROCEDURES – CT & MRI

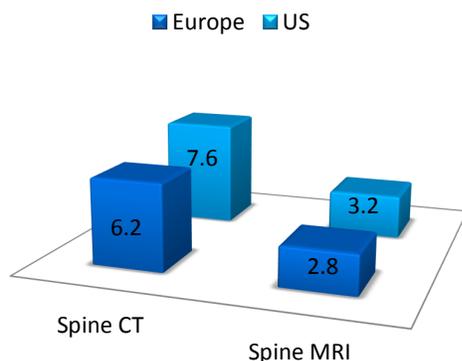
Although guidelines do not recommend, there is a high rate of referrals to diagnostic imaging. Although imaging is related to radiation exposure, referrals to diagnostic imaging are misused if diagnosis rate of LBP is currently 30%. When utilizing Targo's system, considerations should change, as diagnosis rate is over 70% and is comprehensive, including elements that have never been considered before.

There are ~13K imaging units in the US. In 2012 the total number of imaging procedures was estimated at 127M. When considering that Spine scans are 6% of total scans, it is assumed that there were ~8M Spine scans were performed. With reimbursement rates for Lumber spine CT ranging from \$235-\$354 in the US, Targo is aiming at a market size of \$2.5B, just on the CT imaging. If we add the MRI market, we are looking at a market size just over \$5B.

Targo intends to sell its capital equipment for \$30K and charge additional \$10 fee per use. These numbers suggest a TAM of \$271M only in the US.

The European market is estimated at

Spine Imaging Procedure Volume



LBP MARKET

The LBP prevalence defines Targo's target market and effects its growth. It may seem obvious that Targo is disruptive to the Lumber surgery market, but analyzing this market should also consider reoccurring LBP and Failed Back Syndrome following surgeries. With annual expenditure of \$90B, Targo is entering a very profitable market, where some of the profits derive from unnecessary procedures.

In the next 20 years, the spine industry will be faced with new demographics as world population is getting older. Surgeons and the industry are going to be challenged in addressing patients with a different mix of diagnoses and additional comorbidities. Increased prevalence of comorbidities will be a factor in costs and treatment.

Each year about 90M of Americans suffer activity limiting LBP. There are as high as 500,000 LBP surgeries performed annually in US, by over 20,000 practicing orthopedic surgeons. With 40% reoccurrence of pain prevalence, it seems a questionable treatment for the patient. In reality, doctors and hospitals are making huge profits off the backs of unsuspecting patients who are not told there may be better and cheaper ways to solve their back pain with non-invasive methods. The costs of back surgeries are among the most expensive, and these costs do not include hospitalization, imaging, drugs or medications. For example Lumbar laminectomy: \$18,000, Lumbar spinal fusion: \$34,500, Decompression back surgery: \$24,000.

But as reimbursement policy changes, it looks as if there is no other option than reconsider the spine fusions due to its high costs, poor outcomes and increased disability costs and move towards the evidence-based practice. As it always turns around, Hospital will find the way to profit from alternative treatments and increased volume of imaging diagnostic procedures that facilitate high rate and accurate diagnosis.

5.1.4 MARKET TRENDS AND BARRIERS

The main instance for reimbursement in the US is the Center for Medicaid and Medicare Services (CMS). Third-party insurance programs usually follow the recommendations of CMS with respect to reimbursement rates. CPT Category III codes, reserved for 'emerging technologies', are a good indication of the trends in clinical applications. Emerging clinical applications that have demonstrated clinical benefits first enter the realm of reimbursement as Category III codes before becoming 'routine procedures' with a standard, fully reimbursed Category I code.

The use of ACO in Medicare is still at an early stage, but Radiology groups can take action now to position themselves as more relevant in this new healthcare era. They should start by creating joint ventures with hospitals to become part of an ACO, demonstrate the value of their imaging services, and provide better diagnosis within the workflow limits and within the required quota of procedures per day.

Pressure on costs will also force doctors to manage larger volumes of patients—despite the fact that patient care will become more time-consuming with growing demand for documentation, coordination of care, communication with other specialists and patients, and data review. In an environment where scalability and cost containment are major pain points, deployment of technological solutions may assist in meeting the challenges.

The ability to control data with maximal usability (usually minimal number of mouse-clicks) is considered a great value in the medical imaging market, together with intuitive user interface, process automation and clarity of screen layout having high priority. Manufacturers of Medical Imaging applications take on board end-user feedback on imaging application and leverage this user-friendliness with high levels of customer support, including training, maintenance and installation services, to build the necessary solid customer relationships needed to gain a competitive edge as the dynamics of the market change.

Consumer-driven workflow – advanced visualization tools are moving from the diagnostic room to the referring physician's desktop, they will be further implemented into the EMR, where embedded links would take users to a feature-rich Web viewer. As the industry morphs to cater to referring physicians, we expect that in the near future the workflow will enable better interaction between the referring physician and radiologist allowing him to review the images, and get back to radiologist with more intuitive clinical questions. The radiologist in turn could review the relevant portion of the volume, highlight the ROI and explain the answer to the clinical question with various multimedia approaches. This is a whole different level of service that is consumer-driven rather than producer-driven. The market shifts toward a unified solution allowing radiologist to review studies on a single platform, avoiding back and

forth to a separated viewer, while offering referring physicians such as orthopedic surgeons to have a fully functional toolset available throughout the enterprise.

Thin-client solutions – with the advent of thin-client solutions that eludes expensive, standalone workstations, the technology is branching out beyond radiology, as they allow centralized and unified access without need for dedicated hardware. Thin clients employ client server software architecture allowing full-featured software applications on ordinary computer hardware, since the processing occurs on a central server. IT departments also prefer this type of solution since they don't need to manage workstation-specific hardware. Integration of AV system within the PACS and RIS will allow seamless integration between radiology and the IT departments. The end-user environment is characterized by an ever increasing drive towards efficiency.

Thin-client architecture has allowed the delivery of AV tools to radiologists at their primary reading workstations. But when delivering the tools outside of radiology in this manner automatic processing becomes necessary to further minimize steps and employ forms of intelligent image processing. An increasing number of vendors are offering solutions that can optimize the tools and the images before radiologists review them, thus reduce the burden on end users. Numerous picture archiving and communications systems (PACS) vendors are now integrating AV tools directly on the radiology workspace. Instead of launching a separate application that pulls a separate worklist, the full functionality and power of an AV client is available in a tab while reading images.

In an environment where scalability and cost containment are major pain points, being able to easily deploy these solutions across the enterprise will increase their adoption.

5.1.5 MARKET PENETRATION

Market penetration of Medical device is a challenging task; high production costs, high marketing costs, consumer acceptance, long decision process, complicated integration with current system, demand for a complete featured product, low acceptance of innovation and competitive market are just few of the constraints that Targo is facing. Targo has a structured plan to overcome the barriers, and mitigate commercial risks.

Targo plans to engage ten large known (academic) Medical Centers as beta sites. In parallel Targo intends to expose its system in major conferences such as ECR, RSNA, NASS to name a few. During its first two years Targo intends to publish a number of articles in leading journals. All these should facilitate wide exposure to Targo's unique system and method of diagnosis. Academic acclaim is necessary to commercial adoption of Targo's new approach to LBP diagnosis.

Education and publications are very important to the adoption of this product. As in other new technological products, the target of such information has expanded beyond the radiologist to orthopedists, politicians, insurance companies, NHS and even

patients and the general public. Each group plays a key role in how our new quantitative analysis method is adopted and at what pace. The better each group is exposed and educated, the faster the adoption is likely to occur. It is important for radiologists, primary care physicians, and orthopedists for the obvious reason of effective and more accurate diagnosis. Publications are needed to provide them with the data needed to deploy system and benefit more appropriate diagnosis, which could lead to better treatment as well as elimination of wrongful and unnecessary invasive and noninvasive procedures. Education of the public on the mentioned benefits could lead to an increase in consumer demand, thus providing a willing pool of patients seeking solution for their LBP ongoing suffering.

Targo intends to pursue an early stage strategic collaboration with OEM's of imaging equipment and workstations. Targo intends to recruit major opinion leaders to serve as medical and scientific board. By doing so, Targo will achieve wide recognition in the scientific community. In order to facilitate a valuable initial market penetration, Targo will create a large base of beta testing centers. The beta sites are expected to become the first customers and influence market penetration strategy.

Partnering with PACS or medical imaging vendors will enable Targo to access the end-user through superior sales and distribution channels of these vendors. This partnership also makes the product more marketable to this expanded end-user base as it integrates with a PACS system to offer a more rounded workflow solution than is possible with the software alone. In effect, such a partnership offers a viable way of having the focused sales infrastructure of direct selling without the expense it incurs.

A significant obstacle in the adoption of the quantitative model and applications is the cost of the system. This is exacerbated due to shrinking budgets, declining reimbursement costs and general increase in costs associated with providing solutions with body-part dedicated specifications. In an effort to promote adoption, company will try to cross sell value-added of the thin-client architecture that can be utilized by multiple stations within the hospital or imaging clinic. The cost of capital equipment will be considerably low and the prepaid bundle based on pay-per-use will give benefits/options to the end-user. The increased value of package will facilitate faster market penetration and enable to achieve a larger market share.

Initial sales will be via its beta sites, and clinical research collaborators. During its first years, Targo intends to sell directly to its end users, offering on-site installation and next day service plan. Targo's system will easily integrates within hospital systems and workflow, RIS, HIS, PACS and be HIPAA compliant. Targo's review can be easily stored on a CD or a memory stick, friendly to patient enabling him to fully comprehend its diagnosis, therefore, driving him to be committed to the proposed treatment.

The European market is more concerned with improved patient care. Nevertheless, recent changes in economy have put a huge burden on health systems and cost has

become a leading issue. Generally there are two ways to reimburse a medical device: either the device is recognized as providing a health benefit in its own right, or it is recognized as part of a beneficial procedure. For the former, reimbursement levels will be set for the device itself, but when a device is recognized as part of a procedure, payment for the device must come from within the budget set for the procedure as a whole. Targo's device is recognized as part of a beneficial procedure. Moreover, it will assist NHS to save the huge amount spent on ineffective treatments including surgeries, a painful spot for publicly sponsored health system. Targo also fits in the cost of the existing system.

Recent changes as ACO and PPACA, are promoted by deploying Targo's device. By facilitating high rate of LBP diagnosis, our system supports an evidence based practice and enables accountability to each course of treatment that is chosen by the specialist. Nonetheless, as reimbursement changes toward bundled payment, surgeries may not be as profitable as they used to be, maybe even the contrary. Targo gives the doctor the option of and informed decision, based on accurate diagnosis.

5.2 VALUE PROPOSITION

Our system improves rate and accuracy of LBP diagnosis, making it a market changer as it directly affects all major key players in the field of LBP management and treatment: Medical Centers, Imaging Centers, Orthopedic Centers, Insurance companies and NHS and last but not least patients. All benefit significantly by deploying Targo's system.

Improved management of LBP enables to monitor practice of LBP from the stage the patients attend the primary care physician through the process of diagnosis and efficacy of treatment. It will directly reduce costs related to no or inadequate treatment and improve the standard of care. In the long term it will allow better allocation of funds toward accurate treatment and reduce socioeconomic costs related to LBP, such as compensations and low productivity due to disabling pathology.

Medical imaging centers will benefit from increase of scan volume, as Targo's analysis method will be established as accurate tool to specify the cause of pain, making it key tool for LBP diagnosis. Centers practicing interventional radiology will also benefit as they can directly offer effective minimally invasive treatment, increasing the number of procedures.

Orthopedic centers will be able to allocate budgets to uncontroversial interdisciplinary methods of treatment. The complications related to failed and/or inadequate surgeries may impair profits due to lack of reimbursement on repeated procedures. By offering a wide range of treatments, orthopedic centers can gain a larger share of market, piggy backing on the current trends of alternative treatments that were proven to have similar effectiveness as invasive treatment. Orthopedics will also gain additional

patients who currently do not seek treatment, when diagnosis rate is low and preferred solution is surgery, but will be more inclined to do so when diagnosis will be more accurate and large range of treatment will be available.

Insurance companies as well as NHS will be able to reduce high costs related to reimbursement of pricey invasive procedures, which also carry cost of long hospitalization, as well as reduce costs related to sick leave and disability claims. NHS will avoid refunding repeated procedures following reoccurrence of LBP due to unsuccessful surgeries.

Management of LBP as well as clear and agreed upon guideline to practice, accompanied with high efficacy of imaging diagnosis will encourage patients to seek treatment. The acknowledgment that diagnosis is accurate and treatment is effective encourages patient to be more involved, to actively participate and be committed to treatment, thus contributing to a higher rate of successful treatment, lower reoccurrence, and shorten ill time.

Overall, everyone benefits from higher rate of diagnosis, as it generates profits for all medical, imaging and orthopedic centers. It improves standard of care. It reduced direct costs of unsuccessful and unnecessary treatments. Moreover, it reduces indirect costs of related to prolonged illness, such as compensations and low productivity.

5.3 REVENUE MODEL / BUSINESS MODEL

Targo's intends to sell its system in a dual pricing model; low price on capital equipment and affordable PPU rate or no payment for capital equipment and a slightly higher rate per use. Direct costs are estimated at \$7-10K for hardware and \$9K for software. Targo will offer prepaid bundles adjusted to the medical center or imaging center procedure volume. Additional revenues will be attained from service and upgrade plans as part of the tailor made bundling programs. Targo intends to sell its capital equipment for \$30K and charge additional \$10 fee per use or no payment for capital equipment and \$25 fee per use Annual fee for service and support will range from \$500-\$700

With a fast increase in Primary Care Clinics (20% over the last four years), and an increasing number imaging equipment ownership, Targo could be a significant market driver. There is also an increase in number of patients asking for a conclusive and accurate diagnosis, encouraging physicians to refer patients to imaging procedures. In a research that was conducted 96% of physicians reported that they practice defensive medicine, which means referrals to imaging procedures and to specialists among others, all to avoid malpractice claims.

Diagnostic imaging is the fastest growing component of medical expenditure in the United States, with an annual growth rate of 9% (through 2009). This rate is more than double the rate of general medical procedures (4.1%).

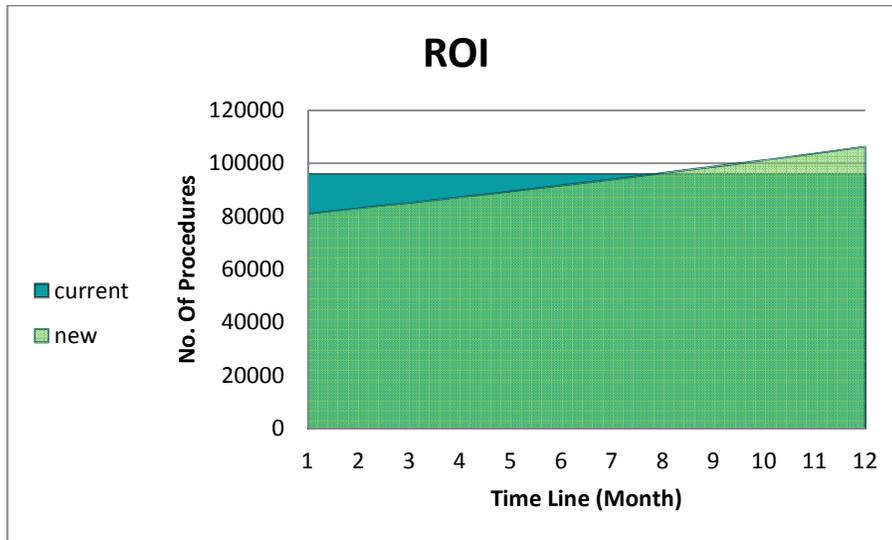
With the competitive atmosphere between medical centers and between the different medical practices to attract more patients, all strive to offer better care, effective treatment and solution to the problem. Rating incorporates all those into a grade that influences patients' decision which medical center or private practice to choose. On the other hand, medical center aims to profit as much as possible from each patient, In order to maximize profitability medical center aims to have an accurate diagnosis, therefore an effective treatment. No diagnosis, no treatment and unhappy patient is losing combination for all parties.

When patients complain to suffer LBP he will be first prescribed with painkillers and rest. If pain continues or causes severe disability patient will be referred to further diagnosis including diagnostic imaging procedure. Following diagnosis process, patient will be referred to either specific treatment (e.g. surgery, minimally invasive procedure or physical therapy), or if no diagnosis was made to conservative treatment (e.g. medication, rest, physical therapy, etc.). Remarkably, for almost all forms of treatment there is reoccurring LBP rate of 40%. When increasing accuracy and rate of LBP diagnosis not only the patient will gain a more effective treatment, but medical center will gain additional treatments (to all these patients with no diagnosis that were not treated).

Targo's system is a market changer; not only because it allows better patient care but because it enables management of LBP, agreed upon guidelines and more profitable procedures to medical centers. Wide adoption of this new concept holds a promise of short ROI, increase revenue and better offering for patients.

5.3.1 ROI MODEL

The company intends to have two optional purchasing alternatives for end users; purchase of capital equipment and low fee of pay-per-use, and no purchasing for a higher fee per use. The agility of both options presents an attractive offering in terms of fund allocation and ROI. Due to its higher rate of diagnosis, utilizing Targo's system will enable to medical center to offer patients an effective treatment, thus gain the profitability of additional procedures. Currently, diagnosis rate as high as 30% allows only small part of the patient to be treated. Nevertheless, gaining additional 40% of accurate diagnosis enables the physician to offer an effective course of treatment either invasive, minimally invasive or noninvasive (physical therapy) with higher rate of success. The following charts suggest optional ROI by center's imaging procedure volume. This ROI incorporates an increase of 50% in medical imaging of LBP over five years, which is expected due the improved ability of the imaging procedure to provide an accurate diagnosis. When full reimbursement of the system will be obtained, ROI will be immediate.



5.4 COMPETITION

The imaging market includes is highly segmented and includes many key players; Imaging equipment OEM's, AV and IT solutions manufacturers.

CT systems OEM's as: Philips Healthcare (Andover, MA), Siemens Healthcare (Malvern, PA), GE Healthcare, Toshiba America Medical Systems, Inc. (Tustin, CA), Hitachi Medical Systems America (Twinsburg, OH). All OEM's hold huge development budget and are in constant race to come up with new technologies and have a competitive advantage.

Workstation, AV and IT solution companies as: Hitachi Medical Systems America (Twinsburg, OH), TeraRecon, Inc. (Foster City, CA) – iNtuition, Vital Images (Minnetonka, MN) – VitreaView, Bayer Healthcare (Tarrytown, NY), Fujifilm Medical Systems U.S.A. (Stamford, CT), Agfa Healthcare (Greenville, SC), Claron Technology (Toronto, Canada), CoActiv Medical (Ridgefield, CT), Del Medical, ETIAM (Cambridge, MA), iCAD, McKesson (San Francisco, CA), Sectra

None of the above companies has developed a competitive product, and most don't have anything (e.g. application, dedicated workflow, or automated algorithms) targeting the spine imaging market. Targo's advantage lays in the innovative concept of its product – re-thinking back diagnosis – offering a quantitative measurement model that provides an accurate diagnosis and supports an effective course of treatment.

Targo's system is a market disruptive to orthopedists surgeons, as we assume it might reduce the number of surgeries performed.

Targo's system is intended to the western world imaging market that is known to be an early adapter of new technologies, and is constantly seeking progress and improvement.

5.5 MASS PRODUCTION

Targo's product BOM is \$12-20K and COGS are estimated at \$25K. Based on off-the-shelf server, Targo has hardly any investment in developing its hardware and can concentrate on developing its nouvelle software. In order to expedite development Targo's algorithm will be integrated in a commercial spine mapper by Claron that will enable DICOM connectivity and volume rendering, in addition to all features that allow customary radiological workflow. Cost of system ranges from \$4K-7K, depending of volume of purchasing. Targo also incurs high marketing and distribution costs; due to on-site installation, calibration and support to end user. Installation and training are expected to take 5-7 working days. We assume that when company moves toward large scale sales, BOM and COGS will reduced by 30%-50%.

5.6 SALES FORECAST

No. of Installation	Y3	Y4	Y5	Y6	Y7
5	\$240,000	\$240,000	\$240,000	\$240,000	\$240,000
10		\$560,000	\$560,000	\$560,000	\$560,000
20			\$1,120,000	\$1,120,000	\$1,120,000
40				\$2,240,000	\$2,240,000
60					\$3,360,000
Total	\$240,000	\$800,000	\$1,920,000	\$4,160,000	\$7,520,000

6 MANAGEMENT AND ORGANIZATION

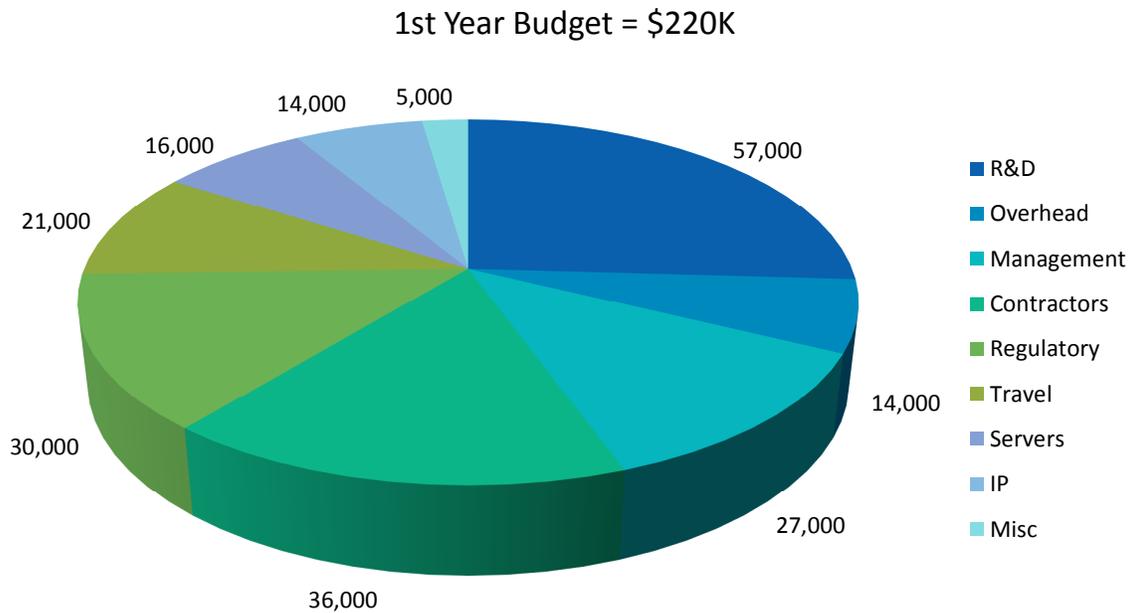
- Board of directors
- Management advisory board
- Attorney
- IP attorney
- Regulatory consultant
- Accountant
- Insurance coverage
- Consultants
- Key advisors

7 BUDGET

Targo's budget is mainly bootstrap (\$70K) owners funds and additional (\$55K) OCS funds. Targo intends to raise \$200K from angels or strategic partners in order to complete first revision of its product. Funds will allow Targo to apply for FDA 510(K) clearance. Funds will allow company to operate 12-18 month while finalizing second funding round. On its second fund raising round; Targo intends to raise \$2.5M, based on company's higher evaluation. Company evaluation should increase dramatically following the completion of first year's tasks.

7.1 FIRST YEAR BUDGET

During the first year following external funding, Targo is operating on a lean budget, aiming to concentrate in raising company's evaluation and mitigating risks. Company will hire only two algorithm researchers and Ori, founder and CEO, will also be part-time participating in algorithmic research. Company will also hire a MA student to conduct clinical study to support R&D and regulatory process. During this year Targo will establish its future beta site collaboration that will also participate in developing product revision 2, the commercial product. Company intends to publish at least one article, and attend major conferences in order to expose its novella method of diagnosis. Academic acclaim eases the adoption of new technologies and new concepts. During this year Targo will file for 510K clearance based on a PACS/workstation predicate. By achieving FDA clearance on its Beta product, Targo is planning to create its one predicate to its commercial revision. Achieving all the above and more will enable Targo to raise its major funding round with a higher evaluation, eliminating technological risks and reducing its commercial stakes.



7.2 NEXT TWO YEAR BUDGET

Item	Q1	Q2	Q3	Q4	Annual Y1	Q5	Q6	Q7	Q8	Annual Y2
CEO	\$35,100	\$35,100	\$35,100	\$35,100	\$140,400	\$35,100	\$35,100	\$35,100	\$35,100	\$140,400
CTO	\$5,070	\$5,070	\$5,070	\$5,070	\$20,280	\$5,070	\$5,070	\$5,070	\$5,070	\$20,280
Biz Dev	\$6,337	\$6,337	\$6,337	\$6,337	\$25,348	\$6,337	\$6,337	\$6,337	\$6,337	\$25,348
R&D Manager	\$30,420	\$30,420	\$30,420	\$30,420	\$121,680	\$30,420	\$30,420	\$30,420	\$30,420	\$121,680
CRA	\$9,360	\$9,360	\$9,360	\$9,360	\$37,440	\$9,360	\$9,360	\$9,360	\$9,360	\$37,440
Office Manager	\$7,800	\$7,800	\$7,800	\$7,800	\$31,200	\$7,800	\$7,800	\$7,800	\$7,800	\$31,200
Total	\$94,087	\$94,087	\$94,087	\$94,087	\$376,348	\$94,087	\$94,087	\$94,087	\$94,087	\$376,348
Senior Alg.	\$25,350	\$25,350	\$25,350	\$25,350	\$101,400	\$25,350	\$25,350	\$25,350	\$25,350	\$101,400
Alg. Dev.			\$21,450	\$21,450	\$42,900	\$21,450	\$21,450	\$21,450	\$21,450	\$85,800
Senior SW	\$22,230	\$22,230	\$22,230	\$22,230	\$88,920	\$22,230	\$22,230	\$22,230	\$22,230	\$88,920
SW Alg.	\$15,600	\$15,600	\$15,600	\$15,600	\$62,400	\$15,600	\$15,600	\$15,600	\$15,600	\$62,400
SW tester		\$9,750	\$9,750	\$9,750	\$29,250	\$9,750	\$9,750	\$9,750	\$9,750	\$39,000
DICOM	\$10,000	\$10,000			\$20,000	\$0	\$0	\$0	\$0	\$0
ISO		\$20,000			\$0	\$20,000	\$0	\$0	\$0	\$20,000
Total	\$73,180	\$102,930	\$94,380	\$94,380	\$344,870	\$114,380	\$94,380	\$94,380	\$94,380	\$397,520
Clinical App.		\$9,750	\$9,750	\$9,750	\$29,250	\$9,750	\$9,750	\$9,750	\$9,750	\$39,000
FDA consultant		\$75,000			\$75,000	\$40,000		\$35,000		\$75,000
Clinical Board	\$15,000	\$15,000	\$15,000	\$15,000	\$60,000	\$15,000	\$15,000	\$15,000	\$15,000	\$60,000
Clinical Research		\$7,500	\$7,500	\$7,500	\$22,500	\$7,500	\$7,500	\$7,500	\$7,500	\$30,000
Total	\$15,000	\$107,250	\$32,250	\$32,250	\$186,750	\$72,250	\$32,250	\$67,250	\$32,250	\$204,000
Office	\$6,000	\$6,000	\$6,000	\$6,000	\$24,000	\$6,000	\$6,000	\$6,000	\$6,000	\$24,000
Supply	\$3,000	\$3,000	\$3,000	\$3,000	\$12,000	\$3,000	\$3,000	\$3,000	\$3,000	\$12,000
CPA / Legal	\$6,000	\$6,000	\$6,000	\$6,000	\$24,000	\$6,000	\$6,000	\$6,000	\$6,000	\$24,000
IP	\$50,000				\$50,000	\$50,000				\$50,000
Total	\$65,000	\$15,000	\$15,000	\$15,000	\$110,000	\$65,000	\$15,000	\$15,000	\$15,000	\$110,000
Graphics	\$10,000				\$10,000	\$0	\$0	\$0	\$0	\$0
Conferences	\$5,000	\$5,000	\$5,000	\$5,000	\$20,000	\$5,000	\$5,000	\$5,000	\$5,000	\$20,000
Literature	\$1,000	\$1,000	\$1,000	\$1,000	\$4,000	\$1,000	\$1,000	\$1,000	\$1,000	\$4,000
total	\$16,000	\$6,000	\$6,000	\$6,000	\$34,000	\$6,000	\$6,000	\$6,000	\$6,000	\$24,000
Computers	\$25,000		\$10,000		\$35,000		\$25,000			\$25,000
Furniture	\$10,000				\$10,000	\$0	\$0	\$0	\$0	\$0
SW	\$10,000				\$10,000	\$10,000				\$10,000
Total	\$45,000	\$0	\$10,000	\$0	\$55,000	\$10,000	\$25,000	\$0	\$0	\$35,000
Total	\$308,267	\$325,267	\$251,717	\$241,717	\$1,106,968	\$361,717	\$266,717	\$276,717	\$241,717	\$1,146,868

Following fund raising of \$2.5M Targo intends to rent offices and start recruiting the necessary team for R&D department and clinical research. On top of the technical and clinical personnel, the company will hire office manager and business development

professionals. Targo allocated funds for the initial investment in equipment such as furniture, computers and other miscellaneous required maintaining office operation and employees requirements. During this 2 year period company will finalize commercial application for CT and start its developing its commercial application for MRI. In order to maximize efficiency and avoid development of unnecessary features, development will be with active collaboration with end users participating in alpha site. Alpha site that were established during the first year of operation (as described in the above paragraph) will support agile development, thus ensure that product comply with end user requirements. Parallel to the development, company will conduct a large clinical study to support its technological research and to provide ongoing data. The budget also includes sufficient funds to allow company to participate in major radiological and spine related conferences in order to expose its innovative approach to LBP and spine disorders diagnosis. Participating in these conferences will allow company to initiate contacts towards its market penetration and sale phase. In order to allow lean budget without compromising progress, company will continue to acquire financial and legal services on a monthly retainer.

Towards the end of the second year of the above described budget, company intends to hire an experienced CEO to assist in round 3 of financing as company commences its commercial stage. 3rd round of financing will be dedicated to market penetration and ongoing sales and support while maintain development team for future products.