Zacks Small-Cap Research

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Bionik Laboratories (BNKL-OTCQX)

BNKL: Initial Revenue. Near-Term Milestones Include ARKE Regulatory Filings, Add'l IMT Product Launches

We value the exoskeleton business at $75M, which is a 10% discount to the average of RWLK and EKSO. We value IMT business at $40M. Sum-of-the-parts values the combined company at $115M, or ~$1.25/share.

Current Price (08/23/16)	$0.92
Valuation	**$1.25**

OUTLOOK

The market for lower-body medical exoskeletons, which is still very much in its infancy, includes a portion of the roughly 3.7M Americans and 10M+ people worldwide living with some form of paralysis. Only a handful of the 20 or more companies developing medical exoskeletons currently have a product on the market and while some are farther along than others in commercialization, none have established a dominant position. We think the market can sustain several players. BNKL recently completed development of its next-gen ARKE exoskeleton. Potential competitive advantages of ARKE include lower price point, ease of use and data analytics. ARKE is expected to enter and complete clinical validation this year. If all goes well it could launch in Canada and Europe in 1H 2017. FDA approval is longer-term goal. We think positive outcomes of certain events including third-party validation, regulatory clearance, and successfully integration of proposed IMT acquisition, among others, could be catalysts to moving the share price higher. IMT products now generating revenue for BNKL.

SUMMARY DATA

52-Week High	**$1.37**
52-Week Low	**$0.51**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**6,712**
Shares Outstanding (mil)	**73**
Market Capitalization ($mil)	**$85**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**36**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**N/A**
P/E using 2018 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med Instruments**

ZACKS ESTIMATES

Revenue
(in 000s of $)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2016	0 A	0 A	0 A	0 A	0 A
2017	164 A	650 E	750 E	150 E	1,714 E
2018					2,100 E
2019					2,450 E

Earnings per Share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2016	-$0.02 A	$0.03 A	$0.02 A	-$0.01 A	$0.01 A
2017	-$0.03 A	-$0.02 E	-$0.03 E	-$0.03 E	-$0.11 E
2018					-$0.12 E
2019					-$0.11 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW…

Fiscal Q1 2017 Financial Results, Business Update:
Bionik announced financial results for their fiscal 2017 first quarter ending June 30, 2016 and provided a business update. Aside from a meaningfully positive variance in operating expenses which came in lower than what we were expecting, financial results were largely inline with our numbers.

As a reminder BNKL closed the acquisition of IMT on April 21. Q1 revenue, all of which is related to sales of IMT's products, came in at $164k, compared to our $200k estimate. IMT's commercialized portfolio contributed approximately $2M of revenue in 2015. We model BNKL fiscal 2017 (ending March 30, 2017) revenue of $1.7M.

Q1 operating expenses were $2.0M ($418k R&D, $1.62M SG&A), compared to our $2.7M estimate ($475k R&D, $2.20M SG&A). Net loss and EPS, excluding $391k non-cash warrant liability revaluation, were $1.9M and ($0.02), compared to our $2.3M and ($0.03) estimates.

Cash used in operating activities in fiscal Q1 was $2.9M ($1.7M ex-changes in working capital). BNKL exited the quarter with $2.7M in cash and equivalents which, along with expected proceeds from sale of IMT products, management believes is sufficient to fund operations for at least the next 12 months.

Recent developments on the operational front include the August announcement of three new key appointments to the commercialization team including Tim McCarthy as Chief Commercialization Officer. Prior to serving as CEO of Medical Compression Systems, Inc. McCarthy was the President and CEO of iWALK, Inc. (BionX Medical Technologies), which is commercializing MIT's novel actively powered lower limb bionic prosthesis. While BionX is privately held, the company and technology were recently featured on Jim Cramer's Mad Money on CNBC (link here.. http://bit.ly/2bK6BLc). Mr. McCarthy who is credited with leading final product development as well as the commercial sales strategy for the BionX product, should be a strong complement to BNKL as they begin preparations for launch of ARKE in their initial territories in Canada and Europe as well as a broader roll-out of IMT's currently (and soon-to-be) commercialized products. Two sales executives, Steven Brown and Jon King, both of which have more than two decades of executive-level sales experience in the rehabilitation and physical medicine segments, also recently came aboard BNKL.

Near-term goals include;

- Continue validation testing of ARKE prepare to make Health Canada and CE Mark regulatory filings
- Complete phase 1 development project with IBM relative to data cloud storage and analytics functionality of ARKE
- IMT products
    - Continue to grow already commercialized products
    - Initial commercialization of InMotion ANKLE
    - Transfer of license related to MIT-Skywalker, a lower extremity product being developed at MIT. Skywalker, a novel device being developed for gait therapy of mobility–challenged individuals (such as stroke and SCI patients), has already completed proof-of-concept. BNKL expects to initiate clinical testing following transfer of the license, which is anticipated to happen later this year.

Other recent highlights include closing of the IMT acquisition (April), presentation of ARKE at the 2016 Colloquium on Sports and People with Disabilities in France (February) and rapid progress with enrollment into the 720-patient RATULS study.

> IMT: As a reminder, in early March BNKL announced the planned acquisition of Interactive Motion Technologies (IMT), a leading innovator of neurorehabilitation robotics. IMT's robotics portfolio, developed at Massachusetts Institute of Technology, currently includes three FDA-approved upper extremity rehabilitation devices as well as two lower body product candidates. IMT, which notes that their robots are the most thoroughly research technology available in the rehabilitation industry, currently generates approximately $2M in annual sales. Their products are sold in more than 20 countries. The acquisition, which closed in April, provides BNKL with an immediate revenue stream, but more importantly a synergistic product portfolio and technology platform as well as key personnel additions.

Per terms of the merger, Bionik assumed all liabilities of IMT and issued a total of 23.65M common shares to IMT shareholders. In addition, BNKL assumes options representing the right to purchase 3M shares of BNKL stock which includes 1M shares with an exercise price of $0.25, 1M shares at $0.95 and 1M shares at $1.05.

Pro forma income statements which, along with a pro forma balance sheet, were filed in an 8-K/A on July 6th and are included in our Appendix, show that IMT generated $1.9M in revenue over the 12 months ending March 31, 2016. We currently model $1.7M of IMT-related revenue in fiscal 2017. Note that our financial model assumes lumpiness in revenue throughout the year (i.e. - we carry the assumption that revenue in the March quarter is relatively soft).

> RATULS: IMT's InMotion robotic gym system is being evaluated in a large UK-based study funded by the NIHR Health Technology Assessment Programme. Enrollment of the Robot Assisted Training for the Upper Limb after Stroke (RATULS) study, which commenced in April 2014, reached the 50% mark in June. Full enrollment of the study, which will include 720 stroke patients, is expected to happen by the end of 2018 and results could be published sometime the following year.

RATULS is a multi-center, randomized controlled study designed to evaluate the effectiveness of robotic-assisted training on upper limb function in stroke patients. Participants will be randomized to one of three arms; robot-assisted training using the InMotion robotic gym system, enhanced upper limb therapy and standard NHS rehabilitation. Effectiveness of robotic-assisted training will be compared to the other two therapies as measured by upper limb function. Primary endpoint is improvement in upper limb function at three months as measured by the Action Research Arm Test (ARAT). Secondary endpoints include additional improvement in function measures as well as health economics and patient and clinician satisfaction scores. The study should provide greater insight into the InMotion products' utility in rehabilitation and, assuming results are positive, could be significant in terms of further validation of the technology as well as in affording potentially positive commercial awareness and demand benefits.

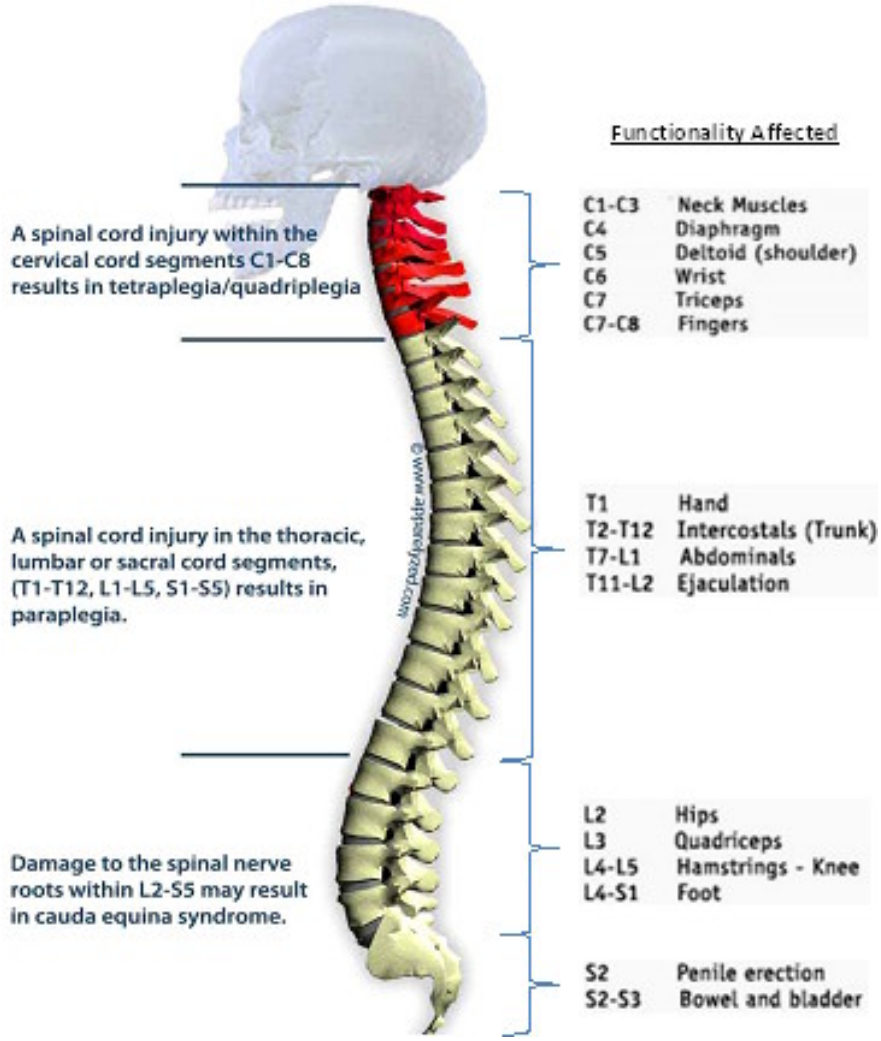
BACKGROUND

Spinal Cord Injuries

It is believed that there are between 270k and 1.3 million Americans living with some form of spinal cord injury. The most common causes are motor vehicle accidents, work-related accidents and injuries caused while participating in sporting or recreational activities. Many people that suffer an SCI will be permanently disabled, may require life-long mobility assistance and undergo regular physical and rehabilitation therapy.

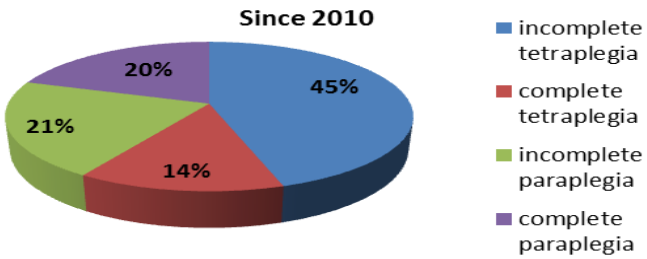
When the spinal cord is damaged messages that travel from the area below the level of the lesion (i.e. injury) through sensory pathways to the brain will be impeded or completed blocked at the location of the injury as will motor messages traveling in the opposite direction. Nerves above the injury level will be unaffected and will continue function as normal.

Spinal cord injuries are categorized by their location and severity. An incomplete injury is one where the individual retains some sensation and function below the area of the injury while a complete injury results in total paralysis below the lesion. Incomplete injuries are further classified by the position of the injury on the spinal cord which can determine the types of functionality and sensation that are lost and retained. These include four categories; Anterior Cord Syndrome, Central Cord Syndrome, Posterior Cord Syndrome and Brown-Sequard Syndrome. While we will not explain each, it is relevant in the context of this report to understand that not all incomplete SCIs are similar with some affording the individual much more function and sensation than others.



In terms of the major classification of SCIs, there is tetraplegia and paraplegia and complete and incomplete injuries of both:

- **tetraplegia**, also known as quadriplegia, is when the injury occurs at the top section of the spine, C1-C8 (see diagram above, source: *Apparelyzed and christopherreeve.org*)
    - per the Foundation for Spinal Cord Injury, Prevention, Care & Cure (FSCIP), incomplete tetraplegia accounts for approximately 45% of SCIs
    - complete tetraplegia accounts for approximately 14% of SCIs
- **paraplegia** is when the injury occurs below C8
    - incomplete paraplegia accounts for approximately 21% of SCIs
    - complete paraplegia accounts for approximately 20% of SCIs



SCI-Associated Health Complications and Costs…

In addition to the obvious medical complications and compromise to quality of life immediately following an SCI, there are other health-related risks that commonly arise over time as a result of reduced mobility and changes to way the body functions.

SCI-related complications include: loss of bladder control, urinary tract infections, renal failure, blood clots, autonomic dysreflexia, pressure sores, respiratory problems (difficulty breathing and coughing), pneumonia, muscle atrophy and spasticity, bone loss and emotional problems (depression, feelings of helplessness), among others.

For those patients with incomplete injuries at C7 and lower (i.e.– that have normal movement of shoulders and can extend their arms) rehabilitation therapy, such as gait-training on a treadmill or walking with the help of parallel bars and/or special orthotics (such as Reciprocating Gait Orthosis) is often used to try and mitigate the risk of many of these complications. Exoskeleton therapy provides the additional benefits of independent mobility (psychological as well as utilitarian benefits) and the ability to potentially induce more targeted effort on the part of the patient which may accelerate therapeutic gains in areas such as bone density, pain reduction, bowel/bladder function and others – which we explain in more detail later.

These complications contribute to a very high rehospitalization rate of SCI patients. According to the Model Spinal Cord Injury Systems Database, 55% of patients in the first year following the SCI incident were readmitted to the hospital and after the first year the rate moved to about 37% where it remained roughly stable for the next 20 years. Life expectancy is also shorter and related to the severity of the injury and motor functionality (which is a proxy for health risks).

High tetraplegia, in the chart below, is defined by the ASIA Impairment Scale as an injury in C1-C4 which essentially affects the entire body below the head including the neck muscles and diaphragm. Christopher Reeve's suffered a high tetra injury above C3. Low tetraplegia is in C5-C8 and affects everything below the neck muscles and diaphragm.

Life expectancy (years) for post-injury by severity of injury and age at injury											
	For persons who survive the first 24 hours						For persons surviving at least 1 year post-injury				
Age at Injury	No SCI	AIS D—Motor Functional at Any Level	Para	Low Tetra (C5–C8)	High Tetra (C1–C4)	Ventilator Dependent Any Level	AIS D—Motor Functional at Any Level	Para	Low Tetra (C5–C8)	High Tetra (C1–C4)	Ventilator Dependent- Any Level
20	59.3	52.6	45.0	39.9	35.6	19.2	53.0	45.5	40.6	36.9	25.3
40	40.4	34.2	27.6	23.3	19.9	8.7	34.6	28.0	23.9	20.9	12.4
60	23.0	18.0	13.0	10.1	8.0	2.1	18.2	13.3	10.5	8.6	3.9

SOURCE: National Spinal Cord Injury Statistical Center (NSCISC)

According to NCISC and based on statistics from the National SCI Database (established in 1973), pneumomia and septicemia (i.e. sepsis) have had the most significant impact on life expectancy of SCI patients. And while death rates due to cancer, heart disease, stroke, arterial diseases, pulmonary embolus, urinary and digestive diseases, and suicide have fallen over the last 40 years, life expectancy has remained fairly stable over the last several decades due to an increase in mortality from endocrine, metabolic and nutritional diseases, accidents, nervous system diseases, musculoskeletal disorders and mental disorders.

Treatment of the acute and chronic symptoms of SCI and related high rehospitalization rates are costly and, similar to life expectancy, are directly related and positively correlated to the severity of the injury. A study, *Economic Impact of SCI*, published in the journal Topics in Spinal Cord Injury Rehabilitation in 2011, estimated that lifetime treatment and living expenses amount to between $1.6M and $4.7M (depending on the severity of the injury) for someone injured at the age of 25 (chart below).

In addition, according to the NSCISC, by developing therapies for those who are already spinal cord injured and preventing new injuries, the U.S. would save as much as $400B on future direct and indirect SCI lifetime costs.

	Average Yearly Expenses (in 2014 dollars)		Estimated Lifetime Costs by Age At Injury (discounted at 2%)	
Severity of Injury	First Year	Each Subsequent Year	25 years old	50 years old
High Tetraplegia (C1–C4) AIS ABC	$1,064,716	$184,891	$4,724,181	$2,596,329
Low Tetraplegia (C5–C8) AIS ABC	$769,351	$113,423	$3,451,781	$2,123,154
Paraplegia AIS ABC	$518,904	$68,739	$2,310,104	$1,516,052
Motor Functional at Any Level AIS D	$347,484	$42,206	$1,578,274	$1,113,990

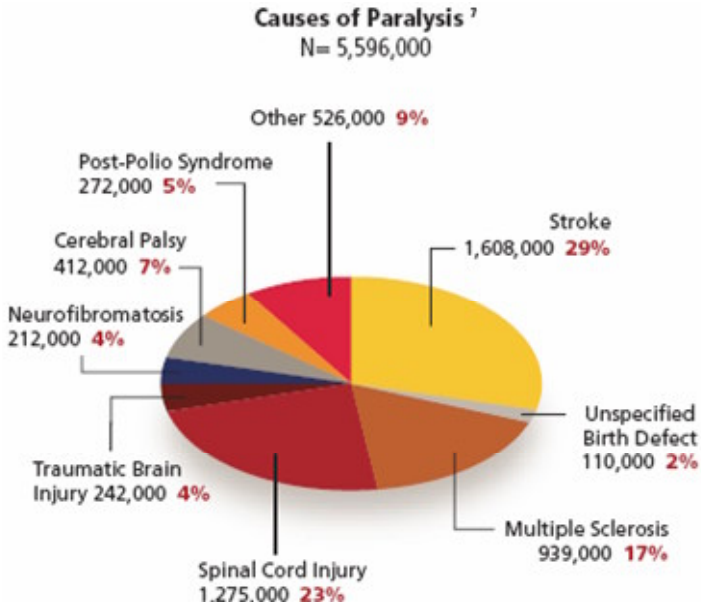
SCI Prevalence / Incidence…

There have not been recent U.S. incidence studies so statistics on the number of people with spinal cord injuries is unknown and, depending on the source, the figures can vary widely. The National Spinal Cord Injury Statistical Center estimates that every year approximately 40 per one million people, or ~12.5k, suffer a spinal cord injury – this figure excludes those that die at the scene. They estimate U.S. prevalence at about 270k people. However, statistics from the Christopher Reeve Foundation, which claims that there are over one million more people in the U.S. living with paralysis than previously thought, indicates that there are almost 1.3M Americans with SCI (i.e. ~5x the NSCISC figure).

We have been unable to find SCI statistics for other territories where Bionik expects to eventually market ARKE (Europe and Canada) although if we apply the U.S. rates, Canadian prevalence could be as high as 150k people and the most marketable countries (i.e. most developed medical device markets) in Europe (UK, Germany, France, Italy, Spain, Netherlands, Denmark, Belgium and Portugal), which aggregate to a total population of ~370M people, could have a combined SCI market slightly larger than that of the U.S.

Other Causes of Paralysis

According to the Christopher Reeve Foundation paralysis, or loss of voluntary muscle movement, encompasses a population of approximately 5.6M people in the U.S. And while most people probably think of SCI when they think of paralysis, the most common cause is actually stroke. Other common causes include multiple sclerosis, cerebral palsy and traumatic brain injury. We provide additional detail on some of these…



SOURCE: christopherreeve.org

- **Stroke**: there are about 1.6M Americans that have been paralyzed from a stroke, accounting for approximately 29% of all paralysis cases. Strokes occur when the brain is deprived of blood and oxygen due to a circulatory obstruction (ischemic stroke) or from rupture of a blood vessel in the brain (hemorrhagic), causing brain cells to die. Injury to the brain can lead to a variety of impairments including to speech and cognition as well as result in paralysis. Paralysis from stroke is usually confined to one side of the body (hemiplegia) and may affect the entire side of the body or just portions – such as the face, arm/hand or leg. Approximately 80% of stroke survivors suffer from hemiplegia, many of which will require the use of ambulatory aids. For more mild cases this may be a cane or walker. For severe cases this may include wheelchairs; conventional manual, hemiplegic manual or electrical. And while 65% to 85% of stroke survivors will learn to walk without the use of ambulatory aids within 6 months, gait abnormalities may persist indefinitely. Studies have found that practicing walking is the activity that consumes the most time in rehabilitation among stroke victims.[1] And time spent walking is time well spent as a separate study revealed that the ability to walk (400 meters) for stroke victims is a predictor of mortality and cardiovascular disease.[2]
- **Multiple Sclerosis**: there are about 940k Americans that have been paralyzed due to MS, accounting for approximately 17% of all paralysis cases. MS is a chronic disease which can be debilitating and one with no cure. In people with MS the body attacks myelin (which surrounds the spinal cord), disrupting nerve impulse transmission. Symptoms can range from somewhat benign to severe, the latter which may include cognition problems, loss of vision and paralysis. While fatigue is very common in almost all MS sufferers, other symptoms and their severity can be highly variable from person to person. MS attacks can come and go in cycles but often becomes progressively worse. Symptom management may include some type of physical therapy to address fatigue and physical deterioration including muscle loss. Approximately 65% of MS sufferers never lose the ability to walk as a result of the disease and 75% never use a wheelchair. There are about 10k new cases of MS diagnosed each year in the U.S. and approximately 400k Americans currently living with the disease.
- **Cerebral Palsy**: there are about 400k Americans that have been paralyzed due to Cerebral Palsy, accounting for approximately 7% of all paralysis cases. Unlike SCI or MS, Cerebral Palsy is not due to damage or deterioration in the spinal cord but is instead a result of inadequate development or damage to areas of the brain that are responsible for movement and posture. CP appears very early in life – usually during pregnancy or childbirth and is the most common movement disorder in children, occurring in ~2.1 of every 1,000 births. Symptoms vary from mild to severe and can include tremors, muscle weakness and paralysis. The name Cerebral Palsy comes from the German term zerebrale Kinderlähmung, translated as "cerebral child-paralysis". There are currently about 500k Americans that have some symptoms of CP with ~8k babies diagnosed with the disorder in the U.S. every year. A study (n=95k) published in the journal

[1] Latham NK, Jette DU, Slavin M, et al. Physical therapy during stroke rehabilitation for people with different walking abilities. Arch Phys Med Rehabil. 2005;86(12 Suppl 2):S41–S50.
[2] Gill TM, Gahbauer EA, Allore HG, Han L. Transitions between frailty states among community-living older persons. Arch Intern Med. 2006;166(4):418–423

JAMA Pediatrics found that 31% of children with CP required the use of special equipment such as walkers or wheelchairs.[3]

- **Traumatic Brain Injury**: there are about 240k Americans that have been paralyzed due to TBI, accounting for approximately 4% of all paralysis cases. While TBI has recently been in the headlines due to head injuries suffered by professional athletes as well as soldiers, the majority of occurrences are from falls (35%) and auto accidents (17%). According to CDC an estimated 1.7M people annually in the U.S. sustain a TBI and ~5.3M have some form of TBI-related disability. Symptoms of TBI can vary from mild to severe and can include memory and cognition problems, behavioral problems, headaches, depression, neurological damage, paralysis and a permanent vegetative state. Our research has not been able to uncover statistics on the percentage of TBI sufferers that use (or have enough function to use) a wheelchair (and therefore may be candidates for exoskeletons). Certainly a portion of the ~240k TBI-related paralysis victims would be candidates although others, with insufficient functionality or strength, would not.

Bionik

ARKE is now in its second generation (shown below) which has a new design, improved walking gait trajectories and much smaller mechanics and actuator components. ARKE incorporates an intelligent positioning system, using information gathered from sensors located throughout the device to determine (based on weight shift or bending) the movement required by the user. Built of carbon fiber and aluminum (as well as steel) to maximize the weight-to-strength ratio, this second generation machine also has (per BNKL) "the highest possible energy and efficiency through both improved battery density and the power-to-weight ratio of the actuators. ARKE utilizes Bionik's proprietary transmission and actuation system, one of the most powerful robotic devices as compared to similar systems". The machine was designed for seamless upgrade to future next-gen versions by using modular electronic components.

ARKE



SOURCE: bioniklabs.com

Bionik views their machine as much more than something that just helps someone stand, walk or improve blood flow and mobility. They have built ARKE to do all of that but, perhaps just as importantly, to also provide real-time feedback and data analytics to help clinicians make more informed treatment decisions. Sensors attached at various points on the device will (i.e. once development is completed) provide

[3] Boulet S. et al. Health Care Use and Health and Functional Impact of Development Disabilities Among U.S. Children, 1997-2005. *Arch Pediatr Adolesc Med.* 2009;163(1):19-26. doi:10.1001/archpediatrics.2008.506

information on gait, strength and positioning, among other metrics, which will be aggregated, stored in the cloud and analyzed with the help of IBM's (NYSE: IBM) data analytics software which was designed together with Bionik. The data collection, cloud storage and data analytics functionality are still under development and will be incorporated into the ARKE-2 system (current model).

The software incorporated into ARKE is highly complex and despite the Bionik team's technology capabilities, was too complicated to develop in-house – thus the collaboration with IBM. The advantage of the software as compared to conventional paper and chart record-keeping is much more than just convenience, although that is one advantage. The company believes that the additional functionality made possible by the software as well as relatively simple programming through a data interface are major differentiators between ARKE and other medical exoskeletons on the market. This is in addition to what they expect to be a significantly lower selling price than competing devices.

The target market for ARKE includes wheelchair-bound patients suffering from SCI, stroke and other conditions with limited lower-body mobility. Initially BNKL will focus on SCI injuries treated at rehabilitation institutions (as opposed to home-use) for use as a complement or replacement for current rehabilitation methods and devices such as body-weight supported treadmill training, intensive mobility training and neurodevelopment techniques. Other upgrades to ARKE could include partial-assist functionality (which allows for patients to contribute their own power) as well as follow-on indications in other conditions including stroke and TBI.

The goal in the rehab clinic segment is to improve the patient's mobility and health. The focus is on areas such as increasing the individual's range of motion, improving blood flow, slowing muscle and bone density loss, helping bowel/bladder function and mitigating risk of other common health-related complications of mobility-impaired individuals (discussed earlier) such as blood clots and respiratory problems. This could have the effect of reducing the high rate of rehospitalization, reduce total cost of therapy and, most importantly, improve and extend quality of life.

Intellectual Property…

Bionik's intellectual property includes five U.S. and international patents pending and thirteen U.S. provisional patents.

Area Of IP	Status	Filing Year
Algorithms & Control Systems	Filed US & International	2012
Sensory Technology	Filed US & International	2012
Robotics	Filed US & International	2012
Robotics	Filed US & International	2012
Robotics	Filed US & International	2012
Robotics	US Provisional	2014
Cloud Computing	US Provisional	2014
Cloud Computing	US Provisional	2014
Robotics	US Provisional	2014
Robotics	US Provisional	2014
Robotics	US Provisional	2014
Algorithms & Control Systems	US Provisional	2014
Algorithms & Control Systems	US Provisional	2014
Sensory Technology	US Provisional	2014
Algorithms & Control Systems	US Provisional	2014
Robotics	US Provisional	2014
Robotics	US Provisional	2014
Algorithms & Control Systems	US Provisional	2014
Energy	US Provisional	2014

SOURCE: bioniklabs.com

ARKE Regulatory Timelines…

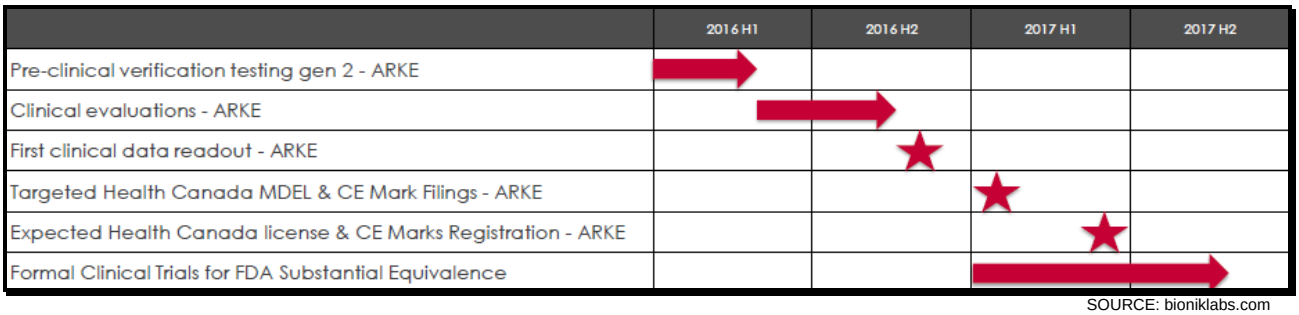
Since the company's founding in 2011 they have been awarded ~$5.5M in grants and Canadian government tax credits (supporting technologies aimed at lowering medical costs). Development has proceeded swiftly with this second-generation model now undergoing pre-clinical validation (assembly and testing).

ARKE will be classified as a Class I device in Canada and Class IIa in Europe. Requirements for CE Marking for low-to-moderate risk medical devices generally relate to the manufacturer self-certifying that the device

meets certain production and quality controls and includes a technical document. And similarly, Health Canada is an informational filing which also is unlikely to require significant clinical data. Once the requisite information is compiled and submitted, clearance to market the device in Europe and Canada could come shortly afterwards.

Clinical evaluations, to demonstrate that a patient can operate the system, will follow the ongoing pre-clinical validation. BNKL's most recent communication regarding expected timelines (March 23, 2016 Update) notes that they anticipate validation to continue through 2016 and hope to file for both Health Canada approval and CE Marking in 1H 2017. If these timelines are met, commercialization in Canada and Europe could initiate as soon as late-2017.

BNKL's Anticipated Regulatory Timelines (as of March 2016)



SOURCE: bioniklabs.com

The U.S. regulatory pathway will almost certainly be more rigorous than Canada and Europe. In February 2015 FDA announced that all powered lower body exoskeletons will be classified as Class II devices and required to meet special controls. The order became effective the following month. The reclassification was prompted by ReWalk Robotics which petitioned the FDA to regulate exoskeletons and classify them as Class II devices. ReWalk's device was the first exoskeleton approved by FDA. As there was no predicate, ReWalk was allowed to use the de novo pathway. ReWalk received FDA clearance in June 2014 for home use (SCI injuries between T7 and L5) and rehabilitation institutions (SCI injuries as high as T4).

The special controls (full list here http://1.usa.gov/1I3SXji) includes testing to demonstrate that it performs as intended and is safe. So BNKL will need to perform clinical studies to support an FDA filing demonstrating that ARKE meets all of these special controls. The expectation is that this will be a 510(k) submission and list ReWalk Rehabilitation as the predicate device. The game plan for the U.S. is to gain approval in the least arduous indication and after commercialized, look to potentially expand the label. BNKL has indicated that they will pursue SCI for ambulation in the rehabilitation setting as the initial indication. Longer-term, they may look to expand the label to include use in other conditions such as stroke, MS and TBI, and to seek approval for the home use setting.

The company has not specified what they anticipate in terms of the scope of U.S. trials although we can use ReWalk's studies supporting their FDA submission as a potential proxy. ReWalk performed three single-arm clinical studies which, in aggregate, included 35 patients who finished the studies. Inclusion criteria in two of the studies were individuals with injury locations at C7-C8 or T1-T12. The third study included only injuries at T1-T12. All three studies included individuals with neurological injuries due to SCI.

- **Studies 1 (n=6) and 2 (n=22):**
  - Primary endpoints: 10 meter walk test (10MWT), 6 minute walk test (6MWT)
  - Secondary endpoint: spasticity as measured by Ashworth scale
  - Methods: 16-24 sessions (~8 weeks) of 60-90 minutes was provided for training on use of the device. Subjects then performed the 10 and 6 meter walk tests. Study 1 (single site) was done on a smooth surface and concrete while Study 2 (2 sites) was done on a larger variety of surfaces which also included carpet and grass as well as some subjects ambulating up and down a ramp and curb cutouts
  - Results:
    - Study 1: 6 patients ambulated 10 to 79 meters in the 6MWT. In the 10MWT these 6 patients ambulated 10 meters in 40 to 163 seconds. Four of the patients recorded no average change in average Ashworth score, while two had a decrease in average score. Skin lesions and falls were also recorded: 3 patients had a combined 13 lesions, no falls were reported

- Study 2: 20 patients ambulated from 0 to 100+ meters in the 6MWT. In the 10MWT 22 patients ambulated 10 meters in 10 to 100+ seconds. 13 subjects recorded an Ashworth score: 8 had no average change, one had an increase and 4 a decrease. Skin tears; six incidents in five subjects. No falls reported

- **Study 3 (n=7):**
  - Primary endpoint: 10MWT, 6MWT and pivot turns
  - Secondary endpoint: arresting on gait command, maneuvering to a wall rest, walking on carpet, navigating a push button electric door, navigating a revolving door, outdoor ambulation and stairs.
  - Results: 6MWT: ambulated from 51 to 166 meters in 6 minutes. 10MWT: ambulated 10 meters in 20 to 62 seconds. Three of the seven had mild skin abrasions and two of seven had moderate abrasions. No falls reported.

Initiation of U.S Regulatory Program Dependent On First Raising Additional Capital…
ReWalk's Study 1 is most consistent with the conditions of what would be expected in the rehabilitation institution setting as ambulation was only done on smooth surface and concrete. By contrast, Studies 2 and 3 were performed on other surfaces and conditions that are more likely to be encountered in a less controlled environment such as the home. As BNKL will initially only pursue clearance for the rehabilitation setting, the requisite clinical support may be just a small (i.e. $n \leq 10$) single-arm, single-site study demonstrating that subjects can use the device as intended which, by default, may be the 6MWT and 10MWT tests.

Timing for start of the U.S. regulatory program will depend on BNKL first raising additional capital. A general guide on what to expect in terms of how long a U.S. program may take can be gleaned from ReWalk's experience. The 6-patient ReWalk study spanned about 11 months from start to finish. If we assume a similar timeframe, ballpark about 6 months for study design and site preparation, 6 months for final data analysis, preparation of the filing (including aggregating all other special controls information) and FDA submission and another 6 months for turnaround of FDA clearance, BNKL could be looking at ~2.5 years from initiation to FDA approval. But this is hypothetical until (at the very least) there is more clarity on what to expect in terms of U.S. studies and, in the more near-term, if and when BNKL will even pursue the U.S. market (which, again, will not happen prior to raising additional capital).

Assuming eventual FDA clearance, BNKL would likely be required to conduct a post-marketing study, as ReWalk did. The post-marketing study collects data on rates of adverse events from real-world use during initial commercialization to ensure that the device can be used safely.

R&D Pipeline…
Following securing an initial indication in SCI-related paraplegic rehabilitation, BNKL's current outlook is that they will look to expand ARKE's label to include rehabilitative use for other conditions including stroke and TBI. The plan is that the next-generation model (i.e. "ARKE 3"), a variable assist product which will incorporate hemiplegic functionality in which only one side (i.e. leg) of the device provides assistance, will target the stroke market. Upgrades to add more functionality for TBI, among others including MS and CP, could follow.

Interactive Motion Technologies: BNKL has other irons in the fire. In early March they announced the planned acquisition of Interactive Motion Technologies, a leading innovator of neurorehabilitation robotics. IMT's robotics portfolio, developed at Massachusetts Institute of Technology, currently includes three FDA-approved upper extremity rehabilitation devices as well as two lower body product candidates. IMT, which notes that their robots "are the most thoroughly research technology available in the rehabilitation industry", currently generates approximately $2M in annual sales. The acquisition, which closed in April provides BNKL with an immediate revenue stream (we model $1.7M of IMT-related revenue in fiscal 2017 ending March 31, 2017), but more importantly a synergistic product portfolio and technology platform as well as key personnel additions.

Boston-based Interactive Motion Technologies is a thought and technology leader in rehabilitation robotics. The company has working partnerships with the Massachusetts Institute of Technology and some of the leading rehabilitation experts around the world. Their InMotion upper body rehabilitation robots have been validated through dozens of controlled clinical studies, including large randomized clinical trials.

The technology was designed around the latest neuroscience research including motor learning and memory. InMotion robots receive patient movement feedback from sensors and then respond according to the individuals' abilities by guiding an appropriate exercise therapy. As a patient's mobility improves, the robots

automatically respond by providing less assistance, ensuring the individual continues to employ effort which furthers the rehabilitation gains. The robots also have a form of variable assist functionality which helps an otherwise immobile patient to initiate movement. Clinicians are able to track patients' progress from quantifiable feedback.

Clearly IMT's product portfolio offers synergies with that of ARKE, the most obvious of which is that sales channels and customer call points (i.e. rehabilitation hospitals and clinics) are similar. But also, Bionik almost certainly viewed the potential to leverage IMT's knowledge and technology in further development of ARKE as an important consideration. Expected future upgrades to ARKE include data feedback and variable assist – similar features which are incorporated into the InMotion robots. And while upgrades to ARKE may be on a different platform, IMT's expertise in the field should be an asset in facilitating further development of Bioniks' exoskeletons. In addition, IMT's U.S.-based manufacturing facility is FDA-compliant, which presumably could be used in manufacturing of ARKE.

Bionik retained IMT's office in Massachusetts and IMT's team will be integrated with that of Bionik's. This includes Hermano Krebs, a co-founder of IMT who is also a principal research scientist at MIT's Newman Laboratory for Biomechanics and Human Rehabilitation. Dr. Krebs is considered one of the top thought-leaders in robotic rehabilitation and has published extensively on the subject. Dr. Krebs assumed the role of Chief Science Officer of Bionik. Dr. Neville Hogan, who was an IMT board member was retained as an advisor to Bionik. Dr. Hogan is also a professor at MIT's Newman Laboratory for Biomechanics and Human Rehabilitation. Dr. Hogan's research is focused on neuroscience, rehabilitation and robotics. IMT's former CEO, Jules Fried, assumed the position of VP of Bioniks' U.S. operations.

IMT's currently commercialized products are FDA-approved and sold in over 20 countries, including the U.S. These include;

- **InMotion ARM**: designed for rehabilitation of individuals with upper extremity neurological limitations. IMT notes that ARM is "the most thoroughly research device for upper extremity neurorehabilitation". It has been used by over 1k patients and completed clinical studies for stroke, cerebral palsy and traumatic brain injury.
- **InMotion WRIST**: for wrist rehabilitation which can help patients overcome most forms of hypertonicity (i.e. extreme muscular or arterial tension). Has a range of motion of a normal wrist doing typical, everyday-types of tasks. InMotion WRIST can be used either in isolation or in addition to InMotion ARM.
- **InMotion HAND**: an add-on to InMotion ARM which provides rehabilitation specifically to the hand. Incorporates assist-as-needed (i.e. similar to variable assist) functionality for grasp and release training and rehabilitation.

ARM **WRIST** **HAND**



SOURCE: Interactive Motion Technologies

In addition to these three already commercialized products, IMT has a lower body product which is currently available for research use called InMotion ANKLE as well as MIT-Skywalker, a device being developed at MIT for gait training. Skywalker, a novel device being developed for gait therapy of mobility–challenged individuals (such as stroke and SCI patients), has already completed proof-of-concept. BNKL expects to initiate clinical testing following transfer of the license, which is anticipated to happen later this year.

Per terms of the merger, Bionik assumed all liabilities of IMT and will issue a total of 23.65M common shares to IMT shareholders. In addition, BNKL assumed options representing the right to purchase 3M shares of BNKL stock which includes 1M shares with an exercise price of $0.25, 1M shares at $0.95 and 1M shares at $1.05.

Pro forma income statements which, along with a pro forma balance sheet, were filed in an 8-K/A on July 6th and are included in our Appendix, show that IMT generated $1.9M in revenue over the last 12 months (ending March 31, 2016). This includes $119k of revenue in the final three months (compared to $205k of revenue in the three months ending March 31, 2015). Note that our financial model assumes lumpiness in revenue throughout the year (i.e. - we carry the assumption that revenue in the March quarter is relatively soft).

RATULS: IMT's InMotion robotic gym system is being evaluated in a large UK-based study funded by the NIHR Health Technology Assessment Programme. Enrollment of the Robot Assisted Training for the Upper Limb after Stroke (RATULS) study, which commenced in April 2014, reached the 50% mark in June. Full enrollment of the study, which will include 720 stroke patients, is expected to happen by the end of 2018 and results could be published sometime the following year.

RATULS is a multi-center, randomized controlled study designed to evaluate the effectiveness of robotic-assisted training on upper limb function in stroke patients. Participants will be randomized to one of three arms; robot-assisted training using the InMotion robotic gym system, enhanced upper limb therapy and standard NHS rehabilitation. Effectiveness of robotic-assisted training will be compared to the other two therapies as measured by upper limb function. Primary endpoint is improvement in upper limb function at three months as measured by the Action Research Arm Test (ARAT). Secondary endpoints include additional improvement in function measures as well as health economics and patient and clinician satisfaction scores. The study should provide greater insight into the InMotion products' utility in rehabilitation and, assuming results are positive, could be significant in terms of further validation of the technology as well as in affording potentially positive commercial awareness and demand benefits.

Exoskeleton Market

In addition to medical applications, exoskeletons have also been designed for military and industrial use in order to provide for greater endurance and strength of able-bodied individuals. As Bionik is focused solely on the medical market, we confine our market and competition commentary to this segment.

The medical market for powered exoskeletons is still very much in its infancy. ReWalk was one of the first exoskeletons to market, introduced in the U.S. in 2011 and the only one with FDA clearance for use in both the rehabilitation and home setting. It was CE Marked in 2010. ReWalk is already in its sixth generation model. There are also a handful of other exoskeleton manufacturers with commercialized devices and many more with ongoing development programs – we discuss some of these in greater detail later.

The only-recent introduction of these devices, combined with less-than-robust rates of adoption and a less-than-favorable reimbursement environment in most countries (Japan may be somewhat of an exception) has meant that saturation is not an issue. So the market, which industry research firm Research and Markets predicts will grow from approximately $17M in 2014 to $2.1B by 2021 (a portion of which also relates to non-medical use), for exoskeletons is not only virtually untapped today but ripe for significant growth with evolving positive fundamentals. We discuss what we believe are some of the most relevant aspects of the market.

- **Expanding Indications Beyond SCI**

  Prevalence of SCI-related paraplegia is (depending on the source) anywhere between approximately 100k and 500k in the U.S. and up to another ~700k in the other areas of the world (Canada and parts of Europe) where BNKL may establish a commercial footprint. And while significant, the size of the SCI market pales in comparison to the aggregate population of other conditions that may also be effectively addressed with exoskeletons. This includes individuals that have been paralyzed due to stroke (1.6M U.S. prevalence), MS (940k U.S. prevalence), Cerebral Palsy (400k U.S. prevalence) and TBI (240k U.S. prevalence).

  The next horizon for exoskeletons is beyond SCI. Hemiplegic functionality for stroke victims as well as partial or variable assist (which will be incorporated into ARKE3), which allows the patient to provide some of his own effort, are some of the newer features of exoskeletons which are beginning to broaden the scope of applications beyond the SCI indication. In April 2016 Ekso GT became the first exoskeleton to receive FDA clearance for use with individuals with hemiplegia due to stroke. And further advancements in functionality should facilitate greater inroads towards expanding labels which will afford access to much bigger markets and potentially help speed a transition of exoskeletons from the novel rehabilitation devices that they are today to, perhaps, mainstream everyday mobility aids in the future.

	Estimated Market Size ('000s)			
Condition	U.S.	Europe[1]	Canada	Total
SCI	500	600	100	**1,200**
Stroke	1,600	1,850	320	**3,770**
MS	940	1,100	200	**2,240**
CP	400	460	80	**940**
TBI	240	300	50	**590**
Total	**3,680**	**4,310**	**750**	**8,740**

[1] Includes only UK, GER, FRA, ITA, ESP, DEN, BEL, POR

- **Evolving Technology**

  The first exoskeleton didn't enter the U.S. market until 2011. While revolutionary in many ways, today's exoskeleton technology is still unrefined but has the potential to evolve very rapidly. With continued investment, today's models could soon evoke memories of the old brick cell phones; incredibly expensive (~$4k in 1984), too big, too heavy and unwieldy, slow, cumbersome and all-but impractical (10hrs to charge for 30min talk time). Few would say the same about today's smart phones.

  The exponential speed that technology is evolving in areas such as microprocessor speed, materials engineering to reduce weight-to-strength ratio, new discoveries in battery technology and improvements in sensors means that we could see consistent, significant and rapid advances in exoskeletons' functionality, performance and ease-of-use. And as technology improves costs should decline and promote adoption – this should be particularly true if it helps facilitate more widespread reimbursement.

  The speed of technological progress is an area which could have a significant effect on separating the winners / leaders from the losers / followers in the race to become the exoskeleton market leader. And while most if not all manufacturers likely realize this, some look to be preparing better than others. Modular designs, which Bionik has incorporated into ARKE (as have some others), which allows for replacing or upgrading portions of the system without a full restructuring or rebuild of the entire device, could prove to be key in this regard.

Today?



Tomorrow?



- **Home Use**

  The rehabilitation segment is a fraction of what the home-use market could be. While we have not been able to find a reliable estimate for the number of physical rehabilitation centers in the U.S., there are approximately 5,000 hospitals in America – which is likely a liberal proxy estimate for the number of rehab facilities. And if we assume each center purchases two exoskeletons, this represents a maximum U.S. rehabilitation market of 10k units. Home use, just for an SCI indication, represents a U.S. market 50x as large as the rehabilitation segment, or approximately 500k units (i.e. – estimated number of SCI-paraplegics). The other possible indications (stroke, MS, CP, TBI) represent a higher functioning (in general) population which may find utility of exoskeletons for both rehabilitation and for everyday mobility. So as technology improves to the point where exoskeletons are more practical as mobility aids, demand for the home use market would almost certainly grow. And technological improvements should also bring down costs of the devices, making them more affordable for individual purchase (as opposed to reliance on insurance reimbursement) for use at home.

- **Reimbursement**

The lack of dedicated reimbursement for rehabilitative use or as a mobility aid is a significant headwind to adoption of these devices. Reimbursement is spotty at best, with anecdotal evidence of manufacturers having some success billing under some of the following CMS (i.e. Medicare) rehab-related codes. .

- 97110: Therapeutic exercises to develop strength and endurance, range of motion, and flexibility
- 97112: Neuromuscular re-education of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities
- 97116: Gait training (includes stair climbing)
- 97530: Therapeutic activities, direct (one-on-one) member contact by the provider (use of dynamic activities to improve functional performance)
- 97750: Physical performance test or measurement (e.g., musculoskeletal, functional capacity), with written report
- 97755: Assistive Technology Assessment Assistive Technology Assessment (eg, to restore, augment, or compensate for existing function, optimize functional tasks, and/or maximize environmental accessibility), direct one-on-one contact by provider, with written report
- 97760: orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(s), lower extremity(s), and/or trunk

ReWalk's experience provides some insight…

These are billed in 15 minute increments at an average rate of approximately $35. A rehabilitation session may average 30 to 90 minutes, which would equate to average reimbursement per session under these codes of approximately $140. For out-patient rehab, this may consist of 2 – 3 sessions per week. For a device that costs upwards of $80k - $100k, this level of reimbursement may not be particularly attractive to a rehab clinic – particularly if payment has not been pre-authorized (i.e. if there is risk that the clinic does not get paid).

ReWalk has been one of the most active manufacturers engaged in improving the reimbursement picture so it is worth mentioning their experiences to provide a better understanding of the insurance-related challenges. According to their publicly available investor communications, they point to reimbursement as the most significant contributor to extending the sales cycle.

In December 2015 ReWalk announced that the U.S. Department of Veterans Affairs issued a national policy which allows veterans with SCI injuries and which meet certain physical requirements to obtain a ReWalk Personal system (for home use). The coverage policy also defines exoskeletons as the standard of care for qualifying spinal cord injuries. We note that while this coverage policy only relates to ReWalk, that it is conceivable that if and when other manufacturers gain FDA approval for home use (including potentially Bionik), that similar policies may cover those systems as well.

More data could improve the reimbursement picture…

The lack of a dedicated code or otherwise widespread reimbursement is due to the fact that these are still novel devices and there is still insufficient clinical data demonstrating the benefits of exoskeletons. As such, these devices are still considered experimental by many insurers. Clinical data demonstrating benefits of these devices over conventional therapy such as improved patient outcomes (such as reduction in muscle atrophy), cost savings (overall or reduced hospitalization costs, for example) and improvements to quality of life will be key to improving the payer picture and as support for applying for a dedicated CMS code.

ReWalk has led the charge in that regard. They claim to have the most clinical data to-date of all exoskeleton manufacturers. The VA is also conducting their own study – a large, multi-center 3-year study with the goal of demonstrating the benefits of exoskeleton use by SCI patients. And other manufacturers including Ekso Bionics also have studies ongoing with the goal of improving reimbursement. And while Bionik is coming later to market than others, in a case like this where there is little reimbursement and only front-end type demand, later to market can actually be a benefit, particularly if competitors are able to improve the reimbursement environment prior to Bionik's launch.

VALUATION

Near-term milestones If all goes well data could be available later in 2016 and regulatory filings for Canada and Europe happening in early 2017. Bionik hopes to have marketing approvals in both of these territories in the first half of 2017.

The quest for U.S. regulatory clearance will be more involved and require at least one formal U.S.-based clinical study in order to satisfy all of the special controls requirements. This is also predicated on first raising additional capital. We expect more information regarding what a U.S. regulatory program would entail will be gleaned from a potential future meeting with FDA. Hypothetically, assuming ReWalk Rehabilitation could be cited as a predicate device and a single, small (~n≤10) clinical study would acceptable to support the filing, we think a reasonable timeline from initiation to FDA clearance could be ~2.5 years. This includes approximate estimates of the study design taking about 6 months, 9-12 months to conduct the study, 6 months for data analysis, preparation of the filing (including aggregating all other special controls information) and FDA submission and another 6 months for turnaround of FDA clearance. This, however, will not move forward until at least BNKL has raised sufficient capital to support the cost of the program.

Commercialization: BNKL has provided only general information relative to their plans for commercialization, indicating that they expect to initially leverage the exposure from the clinical evaluations to detail to research centers and key opinion leaders in Canada. Initial strategy will be to generate awareness about ARKE. BNKL may be able to leverage some of IMT's contacts and sales channels (assuming the deal closes) which could be done with a small marketing team. Attendance at industry conferences and events is also likely to be part of the early marketing efforts. Target customers will be hospitals and rehab clinics.

BNKL is already making preparations for commercialization and in August announced three new key appointments to the commercialization team including Tim McCarthy as Chief Commercialization Officer. Prior to serving as CEO of Medical Compression Systems, Inc. McCarthy was the President and CEO of iWALK, Inc. (BionX Medical Technologies), which is commercializing MIT's novel actively powered lower limb bionic prosthesis. Mr. McCarthy who is credited with leading final product development as well as the commercial sales strategy for the BionX product, should be a strong complement to BNKL as they begin preparations for launch of ARKE in their initial territories in Canada and Europe as well as a broader roll-out of IMT's currently (and soon-to-be) commercialized products. Two sales executives, Steven Brown and Jon King, both of which have more than two decades of executive-level sales experience in the rehabilitation and physical medicine segments, also recently came aboard BNKL.

The next phase of the commercialization strategy may entail establishing training centers and building a direct sales force in Canada and, assuming eventual FDA clearance, the U.S. as well. The game plan for Europe will be to sell through third-party distributors.

And as IMT's products offer synergies with that of ARKE, this may provide the benefits of detailing the combined product catalog at the same call points (i.e. rehab centers and hospitals), the ability to leverage existing customer and distributor relationships (both in and outside of the U.S.), additional competitive differentiation from other exoskeleton manufacturers and, most importantly, bolt on additional revenue drivers.

ARKE-Related Financial Model: We think the above regulatory and commercialization timelines may be do-able as the scope of validation and clinical trials should not be particularly burdensome, the company has indicated that they have at least two completed ARKE GEN-2 systems and initiation of clinical validation in Canada should be imminent.

Our model incorporates the following assumptions;

- **ARKE launches**: in Canada in late 2017 and in Europe in 1H 2018. As the feasibility, cost and timing of an FDA regulatory program and subsequent entry into the U.S. market is much more uncertain, we do not currently model any U.S. related revenue. This, as is the case with all of our assumptions, is subject to updating.
- **Revenue**: we model year 1 (fiscal 2018), year 2 (fiscal 2019) and year 3 (fiscal 2020) revenue of $100k, $450k and $925k, respectively. For context, Ekso did over $500k in sales in its first year and $2.9M in its third year. ReWalk did $972k in its second year (the initial year with publicly available data) on the market. Some of the delta between our BNKL forecasted revenue and the much higher levels of RWLK and EKSO relates to an assumed lower placement rate as a result of what we think will be greater

discernment in marketing spend and related focus on profitability with Bionik as compared to the other two companies.

- **Unit placements**: BNKL has indicated that they expect to pursue a leasing/revenue-share as opposed to or (possibly) in addition to an outright sales business model. While leasing may be feasible, until there is more clarity on how the company intends to implement this (which might require some type of asset-backed financing or sell-leaseback arrangement), we incorporate an assumption (which is subject to updating) that systems are sold outright. Using an average ~50k unit sales price (which is based on earlier communications by the company), we model an installed base of approximately 30 systems through the end of fiscal 2020. For context, RWLK and EKSO had installed bases of 211 (104 of which are in rehab centers) and ~170 units, respectively, at the end of 2015.
- **Expenses**: while ReWalk and Ekso have a several-year lead on BNKL in commercialization of their products and could each have installed bases of several hundred units by the time Bionik makes their first sale, neither has demonstrated an ability to profitably scale their businesses. Growing the installed base appears to be the sole goal of ReWalk's and Ekso's business models with little regard to how much it costs to make those sales.

  Both Ekso and ReWalk have spent exorbitantly on sales and marketing to promote their products, for reimbursement-related promotional activities and in general awareness building of exoskeletons which has resulted in massive net losses since their respective product launches.

  We expect BNKL to incur significantly lower SG&A expense as; initial sales efforts will focus on already established relationships in Canada, Europe is expected to be detailed via third-party distribution, IMT's customer and distribution relationships may be exploitable, the "burden" of general awareness building (and related cost) about exoskeletons should be lower and much of the initial legwork towards promotion of more substantial reimbursement should already have been done (although we expect the quest for greater reimbursement will be a many-years long and ongoing process).

  In terms of gross margin, through developing components in-house and utilizing low-cost overseas manufacturing, Bionik believes they can achieve positive gross margins at initial commercialization and scale that with higher production volumes. Per our discussions with Bionik's management, their focus is on reaching profitability and not on reaching a hypothetical level of system placements. With a greater emphasis on expense control we think BNKL may be able to reach a point of break-even at a much lower level of sales than either ESKO or RWLK (this, of course, is hypothetical until proven).

IMT-Related Financial Model: IMT, the acquisition of which closed in April, should provide BNKL with an immediate revenue stream. Pro forma income statements which, along with a pro forma balance sheet, were filed in an 8-K/A on July 6th and are included in our Appendix, show that IMT generated $1.9M in revenue over the last 12 months (ending March 31, 2016) from its three commercialized products. This includes $119k of revenue in the final three months (compared to $205k of revenue in the three months ending March 31, 2015). Note that our financial model assumes lumpiness in revenue throughout the year (i.e. - we carry the assumption that revenue in the March quarter is relatively soft).

It is unclear as to the specifics of the development status of the pipeline product candidates or timelines on when these could potentially reach the commercial market. While we believe the addition of IMT may offer significant synergistic and scalable opportunities to ARKE and Bionic in general, we initially model annual incremental revenue to BNKL near the current $2M level. This is also subject to updating and based on relevant information flow.

Valuation:

We think comp valuation is the most appropriate methodology given the lack of foresight in regards to near-term sales. We feel RWLK and EKSO are the most appropriate comps given that they are mostly pure-play exoskeleton manufacturers for the medical market (we acknowledge EKSO has some aside segmentation), have devices of similar size and weight, are targeting geographies and customers/patient profiles similar to those of BNKL and are also of similar size as Bionik. We have excluded Parker Hannifin and Cyberdyne from our comp cohort as they are not pure play and are many multiples larger than BNKL. Rex, while pure-play and targeting similar markets, was excluded as their device has generated very little interest (as measured by revenue) which may be due to its certain uniqueness including high price and bulkiness.

Comparable ratio analysis is meaningless given the early stage of the companies and related minimal sales and large running operating losses. As such, metrics such as P/S, EV/S, EV/EBITDA and P/E are either highly skewed or return negative values. The market is therefore likely valuing RWLK and EKSO based on

the potential of their technology and business models and how they fit with current and evolving market fundamentals, which we think is a fair proxy for enterprise value.

RWLK and EKSO both trade at market values of approximately $80M. We think that there is very little or possibly negative value in the installed bases of RWLK and EKSO given that these systems were placed at barely better than cost and may actually be more of a cash drain going forward depending on the amount of in-period warranty claims. In fact EKSO's gross margins in their medical device segment narrowed from almost 30% in YE2014 to less than 8% in 2015 due to "increased service related expenses related to an accelerated maintenance program".

If Bionik can manufacture and sell ARKE at a lower price point than competitors' systems and assuming upcoming validation studies confirm a potential benefit in ease of use/programmability, we think these can provide substantive competitive advantages over ReWalk, Ekso GT and other systems. BNKL should also benefit from and be able to leverage off of the awareness building and the reimbursement promotion groundwork laid by its predecessors.

Given the massive ongoing losses and razor-thin margins of both RWLK and EKSO, we think a case could be made that BNKL should be valued at a premium to both. But despite what looks like it may be a better mousetrap (and a potentially better business model), ARKE has yet to be fully validated by a third party and does not yet have regulatory clearance. And the potential lower price point advantage will only be able to be confirmed following commercialization. We assign an approximate 10% discount as a result of these trade-offs and believe an appropriate value of BNKL is 90% of the average of RWLK and ESKO, or ~$75M market capitalization. In addition, we assign a current value of $40M for IMT, representing the value of the commercialized and pipeline portfolios, R&D assets including facilities, intellectual property and library of clinical data. We also assign material value to recent and ongoing progress of the technology in the RATULS study. This does not include realization of potential synergistic benefits of the combined companies – value of which could eventually be significant but which we feel is too early to be able to accurately estimate.

We think there is upside to our valuation with successful completion of the following milestones;

- outcomes of third-party validation. Validation at rehabilitation centers in Canada
- regulatory clearance. Assuming positive clinical validation results come in 2H 2016, BNKL believes they can file for CE Mark and Health Canada approval shortly afterwards and may have marketing clearance in both territories in 1H 2017
- price point. ARKE pricing will depend on cost to manufacture as well as be determined by what the market is willing to pay. Whether this is realizable is something that will not be known until after the system has been commercialized

Other potential catalysts that could benefit the share price include additional competitive upgrades to ARKE, successful integration of IMT and significant growth of their product portfolio (and pipeline), additional synergistic and non-dilutive product acquisitions/licenses, confirmation of our supposition of BNKL's more efficient business model and improvement to market fundamentals (such as reimbursement, greater adoption, etc).

A $115M market capitalization, which equates to ~$1.25/share, is a ~35% premium to the current $0.92 share price. We look for positive outcomes on certain events including those listed above as triggers that could potentially move our target price higher.

APPENDIX

Below is the pro forma balance sheet as well as income statements for the three and twelve month periods ending March 31, 2016 which were filed in an 8-K/A on July 6th. The pro forma income statements were prepared as if the transaction had closed on January 1, 2016 (for three month period) and April 1, 2015 (for 12 month period). The pro formas do not assume any expense benefits through potential synergies or efficiencies which may be realized via combined operations.

Pro Forma 3 Months Ending March 31, 2016

Bionik Laboratories Corp.
Proforma Operations Statement
Three Months ended March 31, 2016

	Bionik	IMT	Proforma Adjustments		Consolidated
Revenue	-	119,341			119,341
Cost of revenue	-	131,640			131,640
Gross profit	-	(12,299)			(12,299)
Operating expenses					
Research & development	343,742	66,569			410,311
Sales and marketing	-	63,908			63,908
General and adminsitrative	1,438,553	450,394	(2,409)	1	
			(144,411)	3	1,742,127
Share based compensation	158,244	-			158,244
Depreciation	14,387	-	2,409	1	16,796
	1,954,926	580,871			2,391,386
Net loss from operations	(1,954,926)	(593,170)			(2,403,685)
Other income (expenses)					
Interest expenses	-	(19,832)	4,488	2	(15,344)
Other income	8,522	-	(4,488)	2	4,034
State taxes	-	(948)			(948)
Foreign exchange loss	71,399	-			71,399
Change in fair value of warrant derivative liability	870,913	-			870,913
Total other income (expenses)	950,834	(20,780)			930,054
Net loss for the period	(1,004,092)	(613,950)			(1,473,631)
Foreign Exchange translation adjustment	-	-			-
Net loss and comprehensive loss for the period	(1,004,092)	(613,950)			(1,473,631)

1. To reclassify IMT depreciation for consistency of financial statement presentation
2. To eliminate interest expense from IMT and other income in Bionik on loans between the two companies
3. To eliminate IMT share based compensation

Pro Forma 12 Months Ending March 31, 2016

Bionik Laboratories Corp.
Proforma Operations Statement
Twelve Months ended March 31, 2016

	Bionik	IMT	Proforma Adjustments		Consolidated
Revenue	-	1,919,779			1,919,779
Cost of revenue	-	1,363,797			1,363,797
Gross profit	-	555,982			555,982
Operating expenses					
Research & development	1,397,554	178,810			1,576,364
Sales and marketing	-	256,046			256,046
General and administrative		1,428,142	(9,908)	1	
	3,676,125		(544,019)	3	4,550,340
Share based compensation	1,495,837		-		1,495,837
Depreciation	63,454		9,908	1	73,362
	6,632,970	1,862,998			7,951,949
Net loss from operations	(6,632,970)	(1,307,016)			(7,395,967)
Other income (expenses)					
Interest income (expenses)	(2,839)	(88,937)	13,587	2	(78,189)
State Taxes		1,421			1,421
Other income	42,173		(13,587)	2	28,586
Foreign Exchange loss	(112,771)				(112,771)
Change in fair value of warrant derivative liability	7,742,555				7,742,555
Total other income (expenses)	7,669,118	(87,516)			7,581,602
Net income (loss) for the period	1,036,148	(1,394,532)			185,635
Foreign Exchange translation adjustment		-			
Net income (loss) and comprehensive income (loss) for the period	1,036,148	(1,394,532)			185,635

1. To reclassify IMT depreciation for consistency of financial statement presentation
2. To eliminate interest expense from IMT and other income in Bionik on loans between the two companies
3. To eliminate IMT share based compensation

Pro Forma Balance Sheet as of March 31, 2016

Bionik Laboratories Corp.
Proforma Balance Sheet
March 31, 2016

	Bionik	IMT	Proforma adjustments		Consolidated
Current Assets					
Cash	5,381,757	9,786			5,391,543
Accounts Receivable, net	-	27,177			27,177
Prepaid expenses and other current assets	231,733	22,615			254,348
Short term advances	125,153		(125,153)	c	-
Loans receivable	379,908		(379,908)	c	-
Due from related parties	41,445				41,445
Inventories		169,325			169,325
	6,159,996	228,903	(505,061)		5,883,838
Property and equipment, net	76,750	6,281			83,031
Other assets	-	4,284			4,284
Unallocated purchase price			1,573,229	d	
			25,306,086		26,879,315
Total Assets	6,236,746	239,468	26,374,254		32,850,468
Current Liabilities					
Accounts Payable	320,871	606,620	(17,329)	c	910,162
Short term advances	-	105,124	(105,124)	c	-
Loans payable to Bionk Laboratories Corp	-	368,750	(368,750)	c	-
Accrued expenses and other current liabilities	515,979	634,719	(13,858)	c	1,136,840
Demand notes payable to officers/directors	-	345,359			345,359
Customer deposits	-	86,487			86,487
Promissory note payable, current portion	-	200,000			200,000
Credit facility payable		21,495			21,495
Warrant derivative liability	5,135,990				5,135,990
	5,972,840	2,368,554	(505,061)		7,836,333
Stockholders' deficit					
Series A reeemable, convertible preferred stock	-	5,192,838	(5,192,838)	b	-
Special Voting Preferred stock	-				-
Common shares	72,591	15,648	(15,648)	b	
			23,650	a	96,241
Additional paid in capital	11,801,146	1,913,318	1,573,229	d	-
			23,153,350	a	
			(1,913,318)	b	36,527,725
Shares to be issued	-	-			-
Accumulated deficit	(11,651,980)	(9,250,890)	9,250,890	b	(11,651,980)
Accumulated other comprehensive income	42,149				42,149
Total stockholders'deficit	263,906	(2,129,086)	26,879,315		25,014,135
					-
Total liabilities and Stockholders deficit	6,236,746	239,468	26,374,254		32,850,468
			-		

(a) On April 21, 2016, Bionik issued or reserved for issuance 23,650,000 share of common stock valued at $23,177,000 which has been accounted for as unallocated purchase price which will be allocated within 365 days of the closing of the transaction
(b) Eliminates the capital stock, additional paid in capital and accumulated deficit of IMT
(c) Eliminates the loan of $368,750 and advances of $105,000 plus accrued interest
(d) Reflects revalued vested options recorded as share based compensation at the date of the Merger of approximately $1,573,229

Bionik Laboratories Corp

	2016 A	Q1 A	Q2 E	Q3 E	Q4 E	2017 E	2018 E	2019 E
Total Revenues	$0.0	$164.2	$650.0	$750.0	$150.0	$1,714.2	$2,100.0	$2,450.0
YOY Growth	-	-	-	-	-	-	*22.5%*	*16.7%*
Cost of Revenues	$0.0	$58.9	$234.0	$270.0	$75.0	$637.9	$795.0	$1,069.0
Gross Income	$0.0	$105.3	$416.0	$480.0	$75.0	$1,076.3	$1,305.0	$1,381.0
Total Gross Margin	-	*64.1%*	*64.0%*	*64.0%*	*50.0%*	*62.8%*	*62.1%*	*56.4%*
R&D	$1,397.5	$417.8	$600.0	$775.0	$825.0	$2,617.8	$3,880.0	$4,144.0
% R&D	-	*254.5%*	*92.3%*	*103.3%*	*550.0%*	*152.7%*	*184.8%*	*169.1%*
SG&A	$5,236.2	$1,615.2	$2,350.0	$2,525.0	$2,375.0	$8,865.2	$10,950.0	$11,825.0
% SG&A	-	*983.7%*	*361.5%*	*336.7%*	*1583.3%*	*517.2%*	*521.4%*	*482.7%*
Operating Income	($6,633.8)	($1,927.7)	($2,534.0)	($2,820.0)	($3,125.0)	($10,406.7)	($13,525.0)	($14,588.0)
Operating Margin	-	*-1174.1%*	*-389.8%*	*-376.0%*	*-2083.3%*	*-607.1%*	*-644.0%*	*-595.4%*
Interest income, net	($2.9)	($15.2)	($16.0)	($12.5)	($12.5)	($56.2)	($25.0)	$0.0
Other income	$42.1	$11.2	$416.0	$10.0	$10.0	$447.2	$18.0	$62.0
Pre-Tax Income	$1,035.3	($2,322.8)	($2,134.0)	($2,822.5)	($3,127.5)	($10,406.8)	($13,532.0)	($14,526.0)
Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	$1,035.3	($2,322.8)	($2,134.0)	($2,822.5)	($3,127.5)	($10,406.8)	($13,532.0)	($14,526.0)
YOY Growth	-	-	-	-	-	-	-	-
Net Margin	-	*-1414.7%*	*-328.3%*	*-376.3%*	*-2085.0%*	*-607.1%*	*-644.4%*	*-592.9%*
EPS	$0.01	($0.03)	($0.02)	($0.03)	($0.03)	($0.11)	($0.12)	($0.11)
YOY Growth	-	-	-	-	-	-	-	-
Diluted Shares O/S	71,555	82,051	90,700	98,360	104,000	93,778	115,000	127,000

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