

Imagion Biosystems Limited (ASX: IBX)

Equity | Australia

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VIRIATHUS[®]

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Company Description:

Imagion is developing and commercializing a proprietary new technology for detecting solid tumor cancers at earlier stages than are possible with traditional medical imaging tools. The MagSense system is non-invasive, affordable and one to two orders of magnitude more sensitive in detecting cancer cells than MRI, Ultrasound or other imaging devices. Imagion expects to begin safety/toxicology studies of its first MagSense product, a test for HER2 breast cancer, during Summer 2018 and commence feasibility studies in humans by year-end. Pivotal clinical trials could commence during 2019 which will create a path forward for regulatory submissions and commercial sales.

The initial application being developed for MagSense technology is staging HER2 breast cancer cells as an alternative to a breast cancer biopsy. The Company is also working on formulations of the targeting nanoparticles that can identify other solid tumors. Breast cancer is Imagion's most advanced program, but the Company also has pre-clinical programs underway in ovarian and prostate cancer. Imagion plans to use cash on its balance sheet to fund preparation for human studies next year and advance its MagSense system into pivotal clinical trials. Success from the earlier studies will be leveraged to secure a licensing agreement with a major industry partner or return to the market for a larger round of financing.

Informational Report Highlights:

- **Technology addresses a huge market for cancer diagnostics.** The global cancer diagnostics market is valued at US\$100 billion and estimated to be growing 7.6% annually. Patient outcomes improve significantly with early detection, but many cancers are not found until the disease is advanced. There is a huge, unmet medical need for a more sensitive technology that can detect early-stage disease when treatment is most effective.
- **Printer and ink model.** The MagSense system consists of a detecting instrument and injectable targeting nanoparticles that are unique to each cancer. Imagion anticipates that the injectable consumable portion of the test will be the primary driver of revenue growth. Consumable will have 70-80% gross margins and create recurring revenues leveraged by the installed instrument base.
- **Opportunities to license technology.** Instead of raising large sums of capital to build a commercial infrastructure, Imagion intends to license its technology to major medical imaging industry players. MagSense technology's greater sensitivity and specificity and proprietary consumable provide an opportunity to achieve recurring revenue and higher margins.

Financial Data (AUD):

Share Price:	0.057
Market Capitalization (mln):	12.41
Shares Outstanding (mln):	217.7
Float (mln):	78.6
Average Volume (90 Day approx.):	0.08
52 Week Range:	0.043 – 0.170
Exchange:	ASX



Recent Milestones:

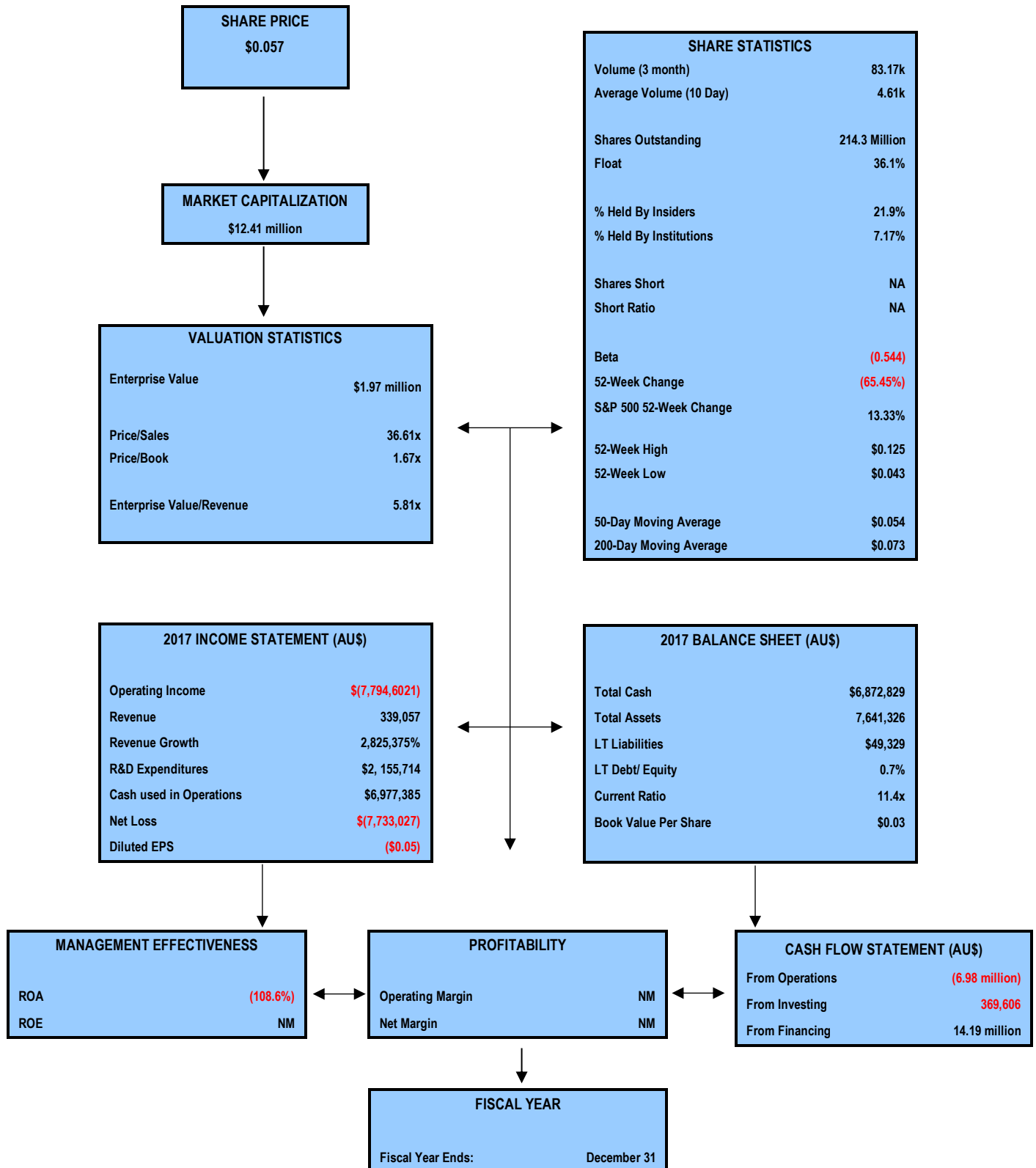
- Received confirmation from FDA that the MagSense system is considered a combination medical device. FDA also accepted Imagion's general toxicology study plan and agreed with the Company's overall clinical study approach.
- Recruits Dr. Farideh Bischoff to lead clinical program as Vice-President of Clinical Research. Dr. Bischoff has prior regulatory and commercialization experience from Biocept and holds a Ph.D. from University of Texas.
- Contracts with ChemConnections to manufacture MagSense nanoparticles for clinical studies and Starfish Medical to design a commercial version of the MagSense instrument.
- Raises A\$12 million through an IPO and lists shares on the Australian Stock Exchange under the symbol IBX. The offering consisted of 60 million shares priced at A\$0.20 per share, valuing the business at A\$43 million.

Balance Sheet (AUS)	December 2017
Cash	6,872,829
Assets	7,641,326
Shareholders' Equity	6,952,556
Non-Current Liabilities	49,329
NCL to Equity Ratio	<1%

P&L Data AUS (000)	2017	2016
Revenues	339	1
R&D	2156	502
Pre-tax Loss	7,795	1,034
Net Loss	7,773	581
EPS	(0.05)	(0.00)

Cash flow: (AUS) (000)	2017	2016
From Operations	6,977	267
Used in Investing	369	0
From Financing	14,185	231

Financial Metrics



Imagion Biosystems Limited
(ASX: IBX)

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Company Overview

Imagion is developing MagSense, a proprietary new imaging technology that addresses clear, unmet medical need for diagnostic imaging tools that can detect early-stage cancer tumors. To-date, the Company has invested approximately US\$18 million in developing its MagSense technology. Pre-clinical studies have established the sensitivity of the technology and its ability to detect cancerous tumors at early stages of the disease. In addition, MagSense technology can specifically locate cancer tumors and stage the disease.

The MagSense system addresses a significant unmet need for a medical imaging tool that can detect, locate and measure cancer tumors at an early stage in their development when treatment is most effective.

The MagSense system consists of a detection instrument platform and a cancer-specific nanoparticle test kit. Both the instrument and consumables component are needed to perform the diagnostic assay. The combination of instrument and consumable reagent creates a printer and ink model that will enable Imagion to generate high-margin recurring revenues from the installed instrument base.

Currently available screening and diagnostic tools are incapable of identifying cancer at early stages, when treatment is most effective. In addition, due to the non-specificity of these screening tools, many patients must undergo expensive and painful surgical biopsies to locate the tumor and differentiate between benign and malignant growths. New blood-based biomarkers are improving detection, but are unable to locate tumors, making additional imaging tools or even surgery necessary to pinpoint and stage the disease.

MagSense technology represents a compelling and cost-effective alternative to the existing standard of care in medical imaging. MagSense is believed to be one to two orders of magnitude more sensitive than MRI or ultrasound in detecting tumors. In addition, capital costs for the MagSense system should be a fraction of the cost of MRI or CT since MagSense uses low magnetic fields that require no radiation shielding.

Imagion's first commercial product will be an imaging diagnostic for staging HER2 breast cancer.

Imagion's first product will be a test for staging HER2 breast cancer. Products for ovarian and prostate cancer are in pre-clinical development. The Company anticipates commencing safety/toxicology studies of the HER2 breast cancer product in the second half of 2018 and undertaking human studies in early 2019. If successful, the feasibility study will be followed by pivotal clinical trials that will involve multiple sites and hundreds of patients. Clinical studies will form the basis for a regulatory submission leading to commercialization. Imagion aims to license applications for MagSense technology to a partner in the medical imaging field who can help provide funding for future product development and clinical trials.

Imagion's go-to-market strategy is to initially launch its HER2 breast cancer product in Australia. By first launching the MagSense system in Australia, Imagion can establish commercial viability that will make the product easier to launch in the US market. The Company also anticipates securing regulatory clearances for the MagSense system in Canada, the UK, Asia and the European Union.

The medical imaging industry is dominated by a few larger players such as GE, Philips and Siemens. Rather than attempting to compete head-on with these companies, Imagion plans to partner with a major competitor. The first step in attracting a commercial partner is establishing the commercial viability of MagSense technology. A successful Australian launch not only de-risks the technology but demonstrates its value and revenue potential.

Products/Technology Overview

Printer/Ink Model

MagSense technology consists of an imaging instrument and a cancer-specific test reagent. This printer/ink model will generate recurring revenues from reagent sales that expand with the installed instrument base.

MagSense technology consists of both a diagnostic imaging instrument and a cancer-specific test reagent. The MagSense system has potential applications across a variety of solid tumor cancers and may also prove useful in the early detection and staging of cardiovascular disease and neurodegenerative disorders such as Parkinson’s disease and Alzheimer’s.

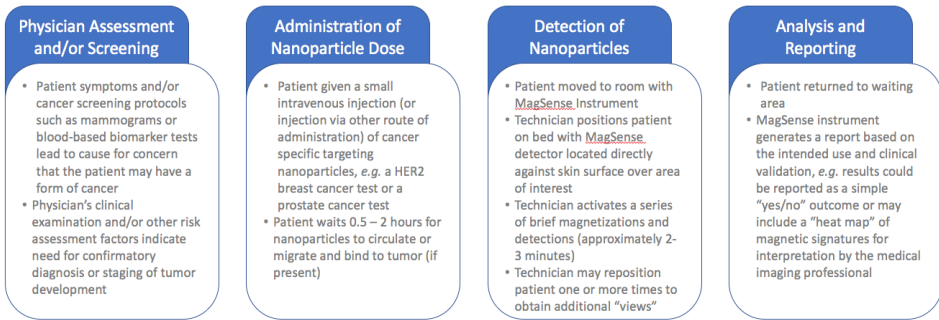
MagSense technology makes use of specialized nanoparticles to locate and quantify diseased cells. These cells are targeted by nanoparticles that are bound with biomarkers (antibodies or small molecules) that attach to specific receptors on the surface of the diseased cell. The bound nanoparticles have a unique magnetic signature that is distinct from unbound nanoparticles or from other cells. Their unique signature allows the MagSense instrument to detect cancerous cells, pinpoint their location, and quantify their numbers without any interference from other structures in the body.

The MagSense instrument magnetizes the cancer-targeting nanoparticles and then measures their state of relaxation 2-3 minutes later. Unbound nanoparticles relax instantly: nanoparticles bound to cancer cells relax at a much slower rate. By measuring the quantity and location of magnetized nanoparticles, MagSense technology can pinpoint and stage cancer tumors.

The same MagSense instrument can be used across a variety of diagnostic tests, but the nanoparticle formulation will be different for each type of cancer.

Imagion plans to develop imaging tests that detect a variety of types of cancer. Each MagSense cancer test will rely on the detection of magnetized nanoparticles and allow the same MagSense instrument to be used to detect different cancers. While the instrument is the same for each test, the nanoparticle formulation will differ. At present, there exists no “pan cancer” biomarker so detecting different kinds of cancer will require formulations of targeting nanoparticle specific to each cancer type.

Graphic 1: Implementation for MagSense Clinical Diagnostic System



MagSense Technology Advantages

The commercial advantages of MagSense technology include greater sensitivity and specificity, non-invasiveness and lower capital costs.

Pre-clinical studies indicate that MagSense technology may be much more sensitive and offer greater specificity than other imaging technologies. Imagion is focusing on commercial applications for its technology as a non-invasive confirmatory diagnostic for specific tumor types. Its initial targets are breast cancer, ovarian cancer and prostate cancer.

The potential advantages of MagSense technology include:

- ✓ *Greater sensitivity and specificity, leading to improved accuracy.* MagSense technology is believed to be one to two orders of magnitude more sensitive in detecting cancer cells than either MRI or Ultrasound. Cancer cells potentially

missed by other detection technologies may be located and staged with MagSense technology.

- ✓ *Non-invasiveness enhances safety.* The nanoparticles used for the MagSense test are manufactured from known bio-safe materials. There are no invasive, painful biopsies or hazards from ionizing radiation.
- ✓ *Lower capital costs increases value proposition.* MagSense instruments use small magnetic coils and a simple localized detector. Capital costs of the machine will likely be a fraction of the cost of CTs and MRIs. In addition, unlike MRI machines, no expensive shielding is required around the MagSense device to block radiation.

Intellectual Property

The FDA has provided guidance that the MagSense system will be classified as a combination medical device.

The Company's patent portfolio, both issued and pending, includes the detection instrument and the magnetically detectable nanoparticles. Imagion holds patents on MagSense technology in the US, Australia, Canada, China, Japan, Russia and Israel, and patents are pending in the US, India, South Korea, and the EU. At present, the Company has seven patents in the US covering fundamental aspects of the technology and six patents outside the US, as well as seven patents pending.

MagSense Nanoparticles

The consumable portion of the MagSense test consists of cancer-specific nanoparticles that will be delivered to the patient via an injectable solution. The solution will contain uniformly-shaped superparamagnetic nanoparticles that have been coated with a protective polymer that allows them to get past the body's immune system and stay in circulation longer. The nanoparticles are formulated with a targeting ligand, such as an antibody, which binds it to the tumor of interest.

Uniform size of the particles is necessary for accurately measuring relaxation time. To ensure uniformity, Imagion has developed a proprietary synthesis method for manufacturing particles within a very narrow tolerance for size, shape and magnetic properties.

Each nanoparticle formulation will be packaged and supplied to the customer as a single-use vial or pre-packaged injectable for use solely with the MagSense instrument. The optimal nanoparticle dose for each cancer test will be determined by clinical studies. In animal studies, Imagion has found that nanoparticle volumes administered to patients have a wide tolerance.

MagSense Instrument

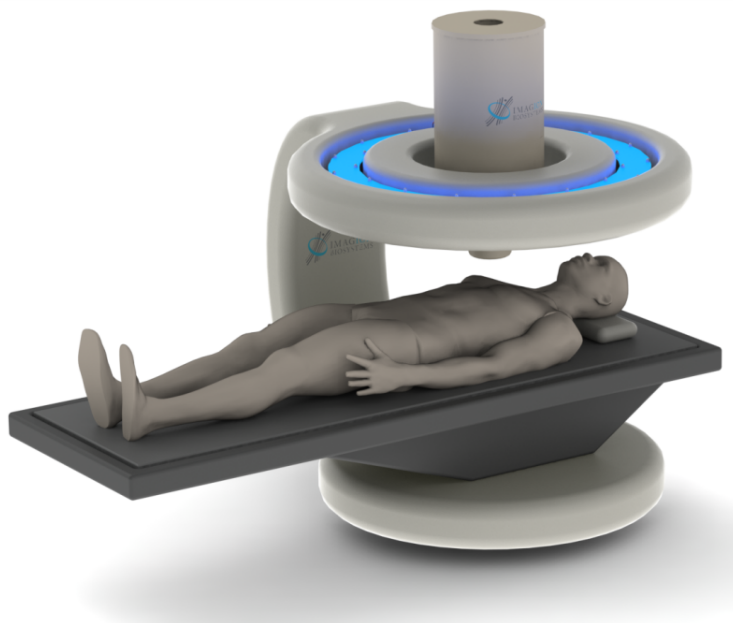
The Company has developed several working prototypes of the MagSense instrument for preclinical use but has not yet designed the commercial instrument. Initial equipment designs have focused on a floor-standing instrument with one or more magnetizing coils and an array of sensors. The first machine will be designed for localized detection of tumors since a smaller configuration is likely to speed time to market. In the future, the Company may develop larger instruments with a bigger detection area, even allowing for full body scans like MRI and CT devices.

The US Food and Drug Administration provided Imagion with guidance indicating that the MagSense instrument and injectable nanoparticles will be classified as a combination medical device. Imagion anticipates the FDA may designate its system as a 510k Class II medical device. The equivalent designation in Australia is a Rule 4.3 Class IIa device by the Therapeutic Goods Administration (TGA). The advantages of 510k designation are faster time-to-market and regulatory submission costs that are a fraction of those for a Class III device. In addition to regulatory submissions in the US

MagSense nanoparticles will be packaged as a single-use vial or prepackaged injectable. The MagSense device will be a floor-standing instrument designed for localized detection of tumors.

and Australia, Imagion plans to seek regulatory clearances from Health Canada and the UK National Health Service and pursue CE Mark designation by the European Union. Management believes that a regulatory submission to TGA Australia will occur prior to other filings since this provides the quickest path to commercialization.

Graphic 2: MagSense Instrument



Initial Product

Imagion has identified its first three cancer targets for MagSense technology and has R&D programs underway in breast, ovarian and prostate cancers that are in various stages of development:

Imagion chose HER2 breast cancer as its initial target because the clinical studies needed to demonstrate superiority to the existing standard of care are straight-forward and don't require large numbers of patients.

- ✓ **Staging of HER2 breast cancer following primary diagnosis.** The MagSense imaging test for HER2 breast cancer test offers a non-invasive lower-cost alternative to lymph node biopsy, which is the method currently being used to stage breast cancer. Early development work on this product was performed through a research collaboration with the University of New Mexico. HER2 breast cancer is the Company's most advanced program. Imagion anticipates commencing toxicology studies in late 2018 and advancing this program to human studies in early 2019.
- ✓ **Detection of ovarian cancer in women with an elevated CA125 blood test.** The MagSense ovarian cancer test is being developed as an alternative to trans-vaginal ultrasound. This program is advancing through a research collaboration with the MD Anderson Cancer Center at the University of Texas and is in early-stage preclinical development.
- ✓ **Detection of prostate cancer in men who have an elevated PSA blood test.** This product may offer an alternative to invasive prostate biopsies. This test is being developed through a research partnership with Cornell University and is in early-stage preclinical development.

HER2 Breast Cancer

By focusing on HER2 Breast cancer as its primary indication, the Company can pursue a path to regulatory approval that requires a small number of trial participants and can be undertaken in a period of less than a year. During the initial human study, results from the MagSense procedure will be compared directly to a pathology report of a biopsy, which is the current standard of care and comparability will be immediately known. Modest in size, these clinical studies will be relatively inexpensive and hasten progress towards a regulatory submission. Imagion's initial success in staging HER2 breast cancer will create a pathway to follow-on studies extending applications for MagSense technology to other tumor types and diseases.

Research programs in ovarian and prostate cancer are in early stages of pre-clinical

The nanoparticles used to detect HER2 breast cancer cells in the patient's lymph nodes will contain 10 mg to 20 mg of iron. This iron load is significantly less than the load used for MRI contrasting or in tests using iron oxide nanoparticle tracers. Additionally, the antibody load on the nanoparticle will be approximately 1/30th of the therapeutic load used for anti-HER2 therapies. As a result, the injectable MagSense nanoparticle solution should be well-tolerated by patients and cause minimal side-effects.

Ovarian and Prostate Cancer

At present, Imagion funds work on other programs such as prostate and ovarian cancer internally. The Company has been working in collaboration with the University of Texas MD Anderson Cancer Center since 2014, which is assisting Imagion in validating its biological models, improving computational algorithms and developing new nanoparticle chemistries under a three-year sponsored research program. MD Anderson Cancer Center is the world's largest cancer research and treatment organization.

MD Anderson recently agreed to convert a significant portion of the sponsored research program fees owed to it by the Company into Imagion shares. The Company plans to issue approximately 10.5 million Imagion shares to MD Anderson in lieu of A\$793k of research program fees. The total amount owed to MD Anderson by the Company is approximately A\$849k. This equity-for-payment arrangement helps both parties by freeing up capital Imagion can use in advancing its research programs and solidifying the relationship between the partners by making MD Anderson an equity stakeholder.

Imagion uses the following criteria to identify specific cancer targets that may be investigated in the future:

- ✓ Solid tumor cancers that have more than 20,000 new cases diagnosed annually. This parameter ensures a sizable market for each cancer test;
- ✓ Cancers for which a known targeting agent or ligand has been identified and FDA-cleared for human use. This criterion minimizes regulatory barriers and helps speed time-to-market;
- ✓ Cancers for which the limits of detection and positioning will pose minimal technical risk; and
- ✓ Indications that minimize the size and time involved in clinical trials.

The same pre-clinical validation steps that were performed for the HER2 program will also be required for each program that follows. Cell-based assays and animal models will reduce the risk of failure as each test progresses to human clinical trials. Although Imagion expects the nanoparticle formulations will be similar for each targeted use, the specific bio-functionality (i.e. ability to bind specifically to the targeted cancer type while providing the sensitivity of detection needed) of each targeting nanoparticle will be determined during pre-clinical testing.

Business Strategy

Over the past decade, the development of MagSense technology has progressed from initial concept and proof-of-principle to pre-clinical study. Imagion is now ready to commence toxicology studies and first-in-human feasibility studies for applications of it technology in HER2 breast cancer. The successful commercialization of this initial product will set the stage for broadening the MagSense technology into other types of cancers, and eventually looking beyond cancer to the diagnoses of other chronic conditions.

The successful commercialization of Imagion's HER2 breast cancer product creates a path for the development and commercialization of other cancer tests.

The Company's near-term operational goals are to:

- ✓ Complete the development of the nanoparticles for safety/toxicology studies and human clinical trials;
- ✓ Continue researching and validating pre-clinical models with applications in prostate, ovarian and other cancers;
- ✓ Identify a licensing or distribution partner who will commercialize MagSense technology or invest in a commercial operation infrastructure to enable direct sales to hospitals.

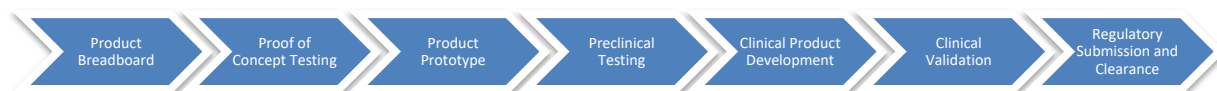
Imagion filed a Pre-Submission document with the FDA in January 2018 and has already received written FDA's feedback, confirming important aspects of its development plan, including:

- ✓ Confirmation that the MagSense system is a combination medical device subject to review by the Center for Devices and Radiological Health;
- ✓ Acceptance of the Company's general toxicology plan and affirmation of its view that the nanoparticle formulation has low safety risk due to prior known safety profiles of the materials used in the formulation;
- ✓ Agreement with Imagion's clinical approach and guidance regarding the first in-human feasibility study design.

Recent steps to advance the breast cancer test include contracting with a nanoparticle manufacturer and commencing safety and toxicology studies.

The next steps the Company needs to take to advance the HER2 breast cancer product into clinical studies are: 1) manufacture an initial batch of GLP-compliant MagSense HER2 nanoparticles and 2) complete a nanoparticle safety and toxicology study. The Company has contracted with Netherlands-based ChemConnections to formulate and manufacture the initial batches of MagSense nanoparticles and anticipates beginning toxicology studies in late 2018.

Graphic 3: Medical Device Development Process



Advance clinical program in HER2breast cancer. Assuming favorable results from the toxicology study, the Company plans to undertake an ex-vivo human clinical study in late 2018, which may be followed by a much larger pivotal human trial beginning in 2019. Management estimates costs for the ex-vivo study will be minimal, and the larger, pivotal trial will cost approximately A\$5 million depending upon the country where the testing is done, the number of patients enrolled and study protocols. The pivotal trial will involve hundreds of patients and at least three sites and will form the basis for a regulatory submission. Imagion plans to license applications for MagSense technology in cancer to an industry partner who will fund the pivotal trial. If a

partnership agreement isn't signed, Imagion may return to the market in 2019 for a larger round of funding to pay for the pivotal trial. The Company may secure bridge financing in 2018 to fund operations while it raises capital to fund the pivotal trial.

Manufacture nanoparticles for clinical trials. Imagion plans to hire a contract research organization (CRO) to conduct safety and toxicology studies of MagSense nanoparticles. The Company believes these studies entail minimal risk since its nanoparticles are similar to the iron oxide nanoparticles already being produced by other companies and used as magnetic contrast agents. In addition, the cancer-targeting biomarkers attached to MagSense nanoparticles have already been cleared for human use.

MagSense nanoparticles must be manufactured to Good Manufacturing Practice (GMP) standards. To this end, the Company has engaged Netherlands-based ChemConnection, a third-party contract manufacturing organization, to produce the targeting nanoparticles that will be needed for toxicology testing and human clinical trials.

The Company has also contracted with Canadian-based Starfish Medical to design and develop a commercial version of the MagSense instrument. Starfish Medical is Canada's leading provider of medical device design, development, and manufacturing services.

Explore additional commercial applications. Imagion is initially targeting applications for MagSense technology in solid tumor cancers but believes there are additional opportunities that could be investigated to build long-term value. These include:

- ✓ Applications in detecting and staging disease targets other than cancer such as neurodegenerative and cardiovascular diseases that can be targeted by biomarkers;
- ✓ Commercializing the technology for use in outside pre-clinical research and clinical studies;
- ✓ Commercializing the technology for veterinary applications;
- ✓ Developing new detectors that improve functionality, i.e. a version of the instrument for full body scanning;
- ✓ Adding therapeutic agents to the nanoparticle formulation that enable both diagnostic and therapeutic treatment.

Imagion is also pursuing opportunities to improve the functionality and utility of the MagSense platform. For example, research and development efforts are underway to increase the functionality of the nanoparticles, which could enable new indications for their use and additional products. The Company is also studying ways to make the MagSense instrument smaller and/or simpler to install and operate. A smaller instrument could allow the installation of MagSense devices in individual physician offices.

Secure a licensing partner. The Company plans to seek one or more partners to commercialize MagSense technology. Potential partners should find the technology attractive as a result of the following:

- ✓ Unlike other imaging tools, the MagSense system consists of both an instrument and a consumable. This printer and ink model will generate recurring revenues that rise with the installed instrument base;
- ✓ Compared to PET, MRI and CT, the MagSense instrument will have lower manufacturing costs, making it more affordable for hospitals and clinics;

StarFish Medical has been hired to design a commercial version of the MagSense instrument.

Imagion plans to seek licensing partners to help commercialize MagSense technology.

- ✓ Due to low magnetic fields, there is no risk of radiation and the MagSense device can be deployed in an unshielded environment. This minimizes installation and capital costs for hospitals and clinics;
- ✓ MagSense could potentially work with smaller magnetic field detectors. This would allow for smaller-sized instruments or even hand-held models;
- ✓ Because of long shelf lives, nanoparticles can be manufactured in bulk to lower costs. High gross margins ranging from 70% to 80% are targeted on consumable sales.

Imagion plans to initiate conversations with potential licensing partners later this year. The Company hopes to publish the results of its first-in-human feasibility study during 2019 and present its findings at the annual meetings of the American Association of Cancer Research (AACR) and the American Society of Clinical Oncology (ASCO). Publishing the study results will put MagSense technology on the radar of potential industry partners and hopefully lead to serious negotiations with one or two candidates as the technology advances into pivotal clinical studies.

Imagion envisions licensing all technology applications in cancer to one partner and seeking additional partners for other diseases and/or variations on the technology.

Assuming a partner licenses MagSense technology and takes responsibility for manufacturing the instrument and nanoparticles, Imagion's compensation will consist of royalty payments likely to range in the low double-digits. If a partner opts to manufacture the instrument and let Imagion manufacture the nanoparticles, payments to Imagion will likely consist of royalties on instrument sales and a revenue-share on consumable sales.

The Company anticipates licensing all the applications for MagSense technology in cancer to one partner and negotiating separate agreements with other licensees for other diseases and/or variations of the instrument. In addition, Imagion envisions opportunities for licensing MagSense technology for veterinary and outside research applications.

The potential pool of industry partners consists of approximately 40 companies that make medical imaging systems and another 20+ companies that have diagnostic products and are potentially interested in entering the medical imaging space via a new technology. The largest medical imaging companies are GE Healthcare, Siemens and Philips. Second-tier players include Elekta and Hologic.

Industry giants such as GE Healthcare and Siemens are stepping up investments in their healthcare businesses, which bodes well for Imagion's licensing prospects. GE recently announced restructuring plans to focus more resources on its aviation, power, and healthcare businesses. Increased investments in healthcare suggest that GE sees this business as critical to its future growth.

The largest medical imaging companies often use M&A and licensing agreements to grow their businesses.

In addition, Siemens recently spun off its healthcare business, raising €4.2 billion from selling a 15 percent stake in the world's largest maker of medical imaging equipment. According to Siemens management, spinning off the healthcare business will accelerate its expansion over the next four years, strengthen its foothold in imaging equipment and promote new areas such as molecular diagnostics that promise faster growth.

Currently available medical imaging technologies have been around for decades, making big scientific or technology breakthroughs on existing platforms unlikely. In this crowded space, organic growth in MRI, CT, PET or ultrasound is limited. To achieve measurable revenue growth, big companies like GE and Siemens must obtain new better technologies through M&A and/or licensing.

Licensing deals usually entail payouts tied to specific development milestones. Imagion doesn't anticipate generating meaningful amounts of revenue until one or

more MagSense products have been commercialized. Sales of the consumable, not the instrument, will likely be the primary driver of its future revenue growth.

Seek third party reimbursement. Securing third party reimbursement is critical to building a sustainable business model worldwide. Imagion plans to seek reimbursement codes for the MagSense device in single-payer healthcare systems such as Australia, Canada and the UK and apply for reimbursement from insurance payers and CMS (Centers for Medicare and Medicaid) in the US. When a medical device is cleared for marketing in Australia, the Australian Department of Health considers its financial impact and consults with the Department of Finance and Deregulation, which may in turn implement a legislative change that adds the device to the Medicare Benefit Schedule. A reimbursement code could establish the MagSense device as the standard of care in Australia. In addition, a reimbursement code in Australia helps define a path for reimbursement codes in other single-payer markets such as Canada and the UK and establishes a framework for reimbursement discussions with CMS.

Imagion plans to launch MagSense products in the Australian market.

Imagion plans to price the MagSense system at less than the available standard-of-care tests. The Company anticipates pricing the injectable nanoparticles at approximately \$1,500 per dose at an 85% gross margin. Factoring in the additional costs of hospital time, staff and the use of the MagSense instrument, Imagion estimates total costs for the MagSense HER2 breast cancer diagnostic at less than \$5,000. This is roughly half the cost of a lymph node biopsy for staging breast cancer.

At present, there is no standard of care in ovarian cancer that compares to the MagSense test. A biopsy of an ovarian cyst can cost as much as \$19,000 in the US. Imagion believes its MagSense product for ovarian cancer is likely to replace transvaginal ultrasound, which is relatively inexpensive (\$500), but far less sensitive than either a biopsy or MagSense test. Considering the availability of the cheaper, but less sensitive alternative technology, Imagion plans to price its product for ovarian cancer at \$750. While this is a fraction of the cost of a biopsy, the primary benefit of the MagSense product for ovarian cancer is its ability to detect ovarian cancer at an earlier stage, enabling treatment to begin sooner and save more lives.

Each successive MagSense cancer test will be priced relative to the existing standard of care for that application.

Imagion plans to price MagSense tests for breast, ovarian and prostate cancer at a discount to existing standard of care products.

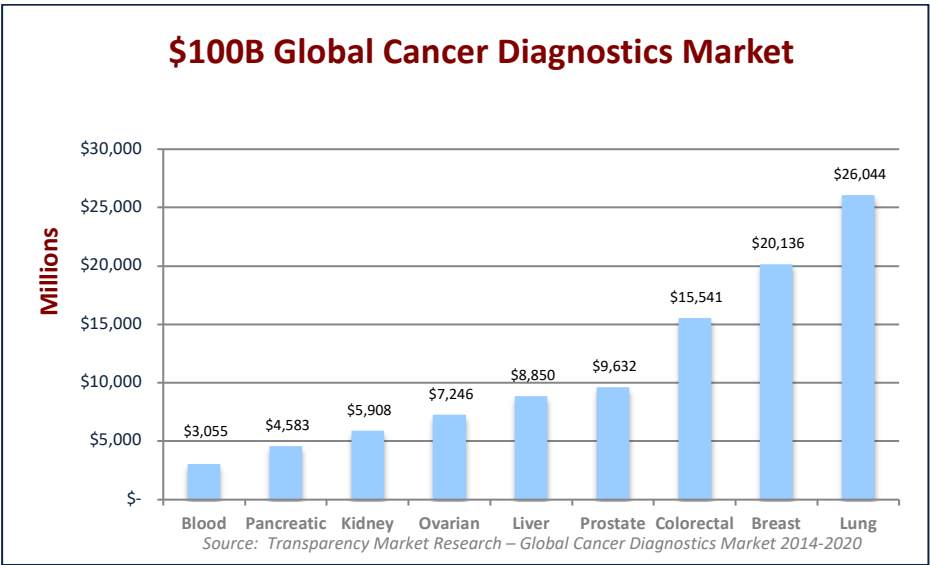
The MagSense instrument will be initially priced at \$400,000. Compared to an MRI instrument, which can cost upwards of \$1 million while also requiring another \$1 million in spending for site engineering costs, installation and special shielding, the MagSense instrument will be much more affordable.

Imagion plans to encourage rapid adoption of MagSense technology by seeding each geographic market (US, Australia, Canada, the UK, etc.) with three MagSense instruments at no cost. MagSense instruments will be placed at leading cancer centers and hospitals, where the Company is performing its pre-clinical and clinical development work.

Market Overview

The global market for cancer diagnostics was valued at approximately \$100 billion in 2013 and is estimated to be growing 7.6%, according to Transparency Market Research. The vast majority of spending is for diagnostic imaging, with biopsy and biomarker testing representing a smaller portion of industry sales. An aging population, unhealthy lifestyles and numerous other factors are contributing to a rising incidence of cancer diagnosis worldwide, which is fueling growth in the global market for cancer diagnostics. The World Health Organization (WHO) estimates that, by 2050, approximately 20 million new cases of cancer will be diagnosed each year. Other factors contributing to the growth of the cancer diagnostics market are new detection techniques and the development of cancer immunotherapies and personalized medicine for determining the most effective treatment for individual patients.

Graphic 4: Growth in the Cancer Diagnostic Market



FDA estimates more than 39 million mammograms are performed in the US each year at an annual cost of roughly \$10 billion.

Imaging tools are often used to screen for cancer and are also sometimes employed to stage cancer tumors, detect relapses and monitor the effectiveness of treatment.

At present, the US is the largest single market for cancer diagnostics, followed by Europe and Asia. However, the Asian market is growing faster as a result of an aging population and healthcare spending in emerging economies like China rising faster to catch up with Western economies.

Traditionally, the primary tools for cancer screening were mammograms, ultrasounds and blood-based biomarker tests. A key drawback of mammograms and ultrasounds is low specificity for cancer. Both require additional testing to confirm the diagnosis and stage the disease. Blood-based biomarkers improve specificity, but still lack the ability to pinpoint the tumor location and stage the disease.

To stage breast cancers, physicians rely on medical imaging or pathology, which involves surgically extracting a tissue sample and analyzing it in a laboratory. Biopsies are reasonably effective at staging cancer, but are invasive, painful and expensive. According to researchers at the MD Anderson Cancer Center and the Peter McCallum Cancer Center, 50% to 70% of patients with HER2 positive breast cancer tumors have

no lymph node involvement, implying that more than half of these patients undergo unnecessary surgery to remove lymph nodes and risk side-effects such as lymphedema and nerve damage related to lymph node removal. In addition, the cost of a lymph node biopsy can range from a few thousand dollars to as much as \$10,000, depending on the complexity of the surgical procedure. MRI imaging to stage breast cancer is painless and non-invasive but limited in sensitivity and specificity and relatively expensive. An MRI can cost upwards of \$5,000.

Imagion is developing applications for MagSense technology in breast, ovarian and prostate cancer:

Breast Cancer

At present, physicians often rely on lymph node biopsies to stage breast cancer. The costs for a lymph node biopsy can run as high as \$10,000 and may cause debilitating side-effects for patients.

According to the National Breast Cancer Foundation, breast cancer is the second leading cause of cancer deaths among American women. The FDA estimates that more than 39 million mammogram procedures are performed in the US each year at an annual cost of approximately \$10 billion. More than 50% of women undergoing an annual mammogram for 10 years will at some point experience a false positive result and many of these women will undergo a lymph node biopsy. The additional costs associated with false positive mammograms are estimated at approximately \$4 billion per year.

Despite the pervasive use of mammograms as a diagnostic tool, many breast cancers are either not detected or detected too late, resulting in more than 500,000 deaths from breast cancer each year. Many of these deaths could be prevented if the disease was diagnosed at an early stage while still treatable. However, due to their lack of sensitivity, mammograms are often unable to detect early-stage breast cancer tumors. The difference in patient outcomes if breast cancer tumors are detected early is significant. National Cancer Institute statistics indicate five-year survival rates of 99% for women whose breast cancer is detected at Stage One (the earliest stage). However, five-year survival rates drop to 24% for women whose cancer is not diagnosed until Stage Four (the final stage). Imagion believes MagSense technology can improve patient outcomes as a result of its ability to detect early-stage breast cancer.

Ovarian Cancer

The American Cancer Society estimates that more than 22,000 US women are diagnosed with ovarian cancer each year and approximately 14,000 women will die from this disease. Although relatively rare, ovarian cancer is the deadliest of all female reproductive cancers. Unlike breast cancer, which is sometimes detected at early stages through screening tools, only about 20% of ovarian cancers are detected at an early and more treatable stage.

Approximately 22,000 US women are diagnosed with ovarian cancer each year. Unlike breast cancer, which is sometimes detected at an early stage, only 20% of ovarian cancers are detected at an earlier, more treatable stage.

Two tests are currently in use to screen for ovarian cancer - TVUS (transvaginal ultrasound) and the CA-125 blood test. TVUS uses sound waves to search for tumors in the ovaries but can't distinguish between cancer and a benign tumor. Costs for a biopsy of an ovarian tumor can run as high as \$19,000, according to Medigo. CA-125 is useful as a marker since this protein is sometimes found at high levels in women with ovarian cancer. However, the CA-125 test is less than effective as a screening tool; many other conditions unrelated to ovarian cancer can produce high CA-125 levels. Imagion believes MagSense technology may offer a safer, more effective and more affordable tool for detecting early stage ovarian cancer.

Prostate Cancer

According to the American Cancer Society, prostate cancer is the second most common cause of cancer deaths among men and a major health threat worldwide. A John Hopkins study estimated that, despite more than one million prostate cancer

biopsies performed in the US each year, less than one-third of these biopsies result in a diagnosis of prostate cancer. Accurate diagnosis comes at a considerable cost to the US healthcare system. Approximately \$4.4 billion annually is spent on screening, diagnosing and staging prostate cancers. A diagnostic tool that is more accurate and affordable would address a huge market opportunity in prostate cancer.

Management & Board of Directors

The underlying business that became Imagion was formed as Senior Scientific LLC, a private US company founded by Dr. Edward Flynn. A former scientist at Los Alamos National Laboratory, Dr. Flynn was a pioneer in the field of magnetic relaxometry. His discoveries served as the platform for developing the MagSense system and he funded proof-of-principle research of the technology.

In June 2011, Senior Scientific was acquired by publicly-traded Manhattan Scientific (OTCQB: MHTX) and spun off and merged into a new US entity (Imagion US), which became a wholly-owned subsidiary of Manhattan Scientific. In December 2016 the Company was incorporated in Australia and a new entity, Imagion, acquired all the shares of Imagion US from Manhattan Scientific in exchange for equity in the business. The new business is led by Robert Proulx, who previously served as President and Chief Operating Officer of Senior Scientific. The backgrounds of Imagion's other board members and corporate officers are discussed below.

Robert Proulx
Executive Chairman

Mr. Proulx has over 25 years of experience in the life sciences and medical device sectors and previously served as President and COO of Imagion's predecessor, Senior Scientific. In addition, he formerly served as President and General Manager of Silicon Biosystems, which developed an image-based liquid biopsy diagnostic platform for circulating tumor cells. Mr. Proulx has sales management and marketing experience from the computer, life sciences and medical device industries. He holds undergraduate and graduate degrees from State University of New York and an Executive MBA from Penn State University.

Mike Harsh
Non-Executive Chairman

Mr. Harsh has nearly 36 years of diagnostic imaging technology experience, primarily with GE Healthcare, where he was Global Technology Leader of Imaging Technologies, overseeing research efforts in X-Ray, CT, MRI, Ultrasound, Nuclear Medicine, PET and Optical Imaging. He has served as a board-level advisor to many technology companies and earlier served as Chief Product Officer of Terapede Systems, an imaging start-up. He is a Fellow of the American Institute for Medical and Biological Engineering and holds a degree in Electrical Engineering from Marquette University.

John Hazle, Ph.D.
Non-Executive Director

Dr. Hazle is Professor and Chairman of the Department of Imaging Physics at the University of Texas MD Anderson Cancer Center. He is a medical physicist, board-certified and licensed in Texas, for both therapeutic and diagnostic medical physics, with over 25 years of related experience. Dr. Hazle is highly sought-after as an academic and business partner, serves on many institutional committees, is a medical imaging expert for multiple industry partners, and is a reviewer for six peer-reviewed scientific journals. He holds a Ph.D. in Biophysics from the University of Texas, Graduate School of Biomedical Sciences.

David Ludvigson
Non-Executive Director

Mr. Ludvigson is a financial expert with deep life science industry experience who has advised many companies regarding M&A, corporate partnerships, OEM arrangements and licensing agreements. He currently serves as President and CEO of Nanomix, a mobile diagnostics company, and previously held executive leadership positions with Nanogen, Matrix Pharmaceutical, IDEC Pharmaceuticals, MIPS Computer Systems and other high-tech companies. He began his career at Price Waterhouse and holds undergraduate and Master's degrees in Accounting from the University of Illinois.

Jovanka Naumoska
Independent Non-Executive Director and Company Secretary

Ms. Naumoska is an Australian-qualified corporate lawyer with board-level experience in legal issues pertaining to medical imaging. She has served as Senior Corporate Lawyer and Policy Advisor for ANSTO (Australian Nuclear Science and Technology Organization) and currently serves as Manager, Business Excellence, overseeing business operations, IP development and regulatory compliance. She also serves on the

board of PETNET Australia, a PET radiopharmaceutical production facility. She obtained her law degree from University of Wollongong and a graduate degree in Corporate Governance from the Governance Institute of Australia.

Mark Van Asten
Independent Non-Executive Director

Mr. Van Asten is an Australian entrepreneur who has more than 30 years of experience in international business development, strategic planning and introducing new technologies. He is Managing Director and founder of Diagnostic Technology Pty Ltd, and has overseen the introduction and adoption of new technologies such as human papillomavirus DNA testing for cervical cancer screening in Australia and Asia. He has held several director-level business development positions with US and Australian companies.

Bronwyn Le Grice
Independent Non-Executive Director

Ms. Le Grice has more than 15 years of experience in healthcare and technology markets spanning venture capital, capital-raising and corporate governance for Australian-listed companies and non-profit organizations. She is currently Managing Director of ANDHealth, a unique industry-led non-profit organization focused on strengthening the Australian digital health network and de-risking innovation in digital health. She previously served as an Investment Director with leading Australian healthcare venture capital firm BioScience Managers, where she was responsible for managing significant transactions in the health technology and digital health sectors, resulting in more than A\$65 million of public and private equity financings.

Guillo Paciotto
Vice-President, Research & Development

Dr. Paciotto has 15 years of experience in developing complex nanoparticle-based medicines to satisfy medical regulatory requirements, including GMP manufacturing, analytical program development, toxicology and new device regulatory submissions. He previously served as Chief Science Officer at CytImmune Sciences and has authored numerous patents in nanotechnology for use in oncology, drug delivery, cancer detection and other uses. He holds a Ph.D. from the University of Maryland.

Dr. Farideh Bischoff
Vice-President, Clinical Research

Dr. Bischoff joined Imagion as Vice-President, Clinical Research in February 2018. She has deep relevant experience in oncology product commercialization and formerly led scientific development, regulatory submission and the successful commercialization of molecular diagnostics at Biocept. In addition, she has led numerous productive collaborative studies, including the NIFTY HIH Fetal Cell Study, composed of individuals from academic, pharmaceutical and biotech organizations.

She is widely recognized the fields of rare cancer cell detection, molecular cytogenetics, diagnostic assay development and validation. She holds a Ph.D. from the University of Texas, Graduate School of Biological Sciences in Houston. Her doctoral thesis led to the discovery of the p53 tumor suppressor gene and the emergence of a productive new avenue of global cancer research.

Brian Conn
Chief Financial Officer

Mr. Conn has more than 25 years of experience in raising capital and advising biotechnology companies on M&A strategies. He previously served as CFO of Verdezyne, where he helped raise over \$170 million of capital. He has also held senior financial management positions with Chemicon International, Serologicals Corp, Millipore, and MicroIslet. He holds a degree in Finance from Arizona State University.

Imagion's officers and directors have good equity stakes in the business. Executive Chairman Bob Proulx purchased 235,000 Imagion shares on the open market last year and also holds 8.7 million performance shares. Officers and directors as a group together own 486,681 equity-settled options that are valued at \$1.23 million and 12.9 million performance shares. The largest single Imagion shareholder is Manhattan Scientific, which owns 64 million shares or approximately 31.5% of the ordinary shares issued.

Competition

The MagSense device competes with other medical imaging technologies that have already been commercialized. There are several imaging technologies in use today, although none are routinely used in a highly targeted manner. Imagion believes it likely that MagSense technology will be used in conjunction with other methods as part of a multi-modal diagnostic protocol.

When compared to MagSense, other imaging technologies lack specificity and the ability to detect small tumors. Some technologies such as MRI, CT and PET, expose the patient to dangerous radiation.

The medical imaging field is dominated by a few large competitors such as GE Healthcare, Siemens and Philips and a second tier of players such as Elekta and Hologic.

The medical imaging technologies most commonly used today are MRI (Magnetic Resonance Imaging), CT (Computed Tomography), PET (Positive Emission Tomography), Ultrasound and Mammogram. Each technology has its distinct advantages and disadvantages, which are discussed below.

Magnetic Resonance Imaging (MRI) provides high-resolution images of soft tissue but is slower and more expensive than CT and can't easily detect smaller tumors for reasonable scan times. This is due to the increased number of phase steps and scan time that would be required.

Computed Tomography (CT) provides relatively fast scan times and high resolution of anatomical features. However, soft tissue contrast resolution is poor and CT, like MRI, exposes the patient to radiation.

Graphic 5: Advantages/Disadvantages of Various Imaging Technologies

	MRI	CT	PET	Ultrasound	Mammograms
Technique	Magnetic Resonance Imaging	Computed Tomography	Positron Emission Tomography	Sonic wave	X-Ray
Best use	High resolution soft tissue imaging	Fast high resolution of anatomical structures	Image areas of high metabolic activity	Inexpensive moderate resolution imaging	Image micro-calcification of breast tissue
Hazards Drawbacks	Expensive Slow Claustrophobia	Expensive Radiation exposure	Use radioactive tracer	High false positives	Radiation exposure Poor sensitivity

Other imaging technologies may identify an area of interest, but only MagSense allows the high specificity needed to minimize false positives.

Positive Emission Tomography (PET) uses a radioactive isotope to target areas of high metabolic activity. Innovations to the base technology attach the radioactive tracer to an antibody or ligand for targeting specific types of tumors. A significant drawback of PET technology, however, is the short half-life of the radioactive PET tracer. This requires that the injectable tracer be manufactured near the PET scanner installation. As a result, a limited number of PET scan facilities have been built.

Ultrasound is often used as a follow-up to screening methods. While relatively inexpensive, ultrasound requires the services of a skilled technician and procedure times can be long. In addition, ultrasounds lack specificity and are not sensitive enough to detect small tumors.

Mammogram makes use of high-resolution projection imaging on equipment designed to detect the small micro-calcifications characteristic of breast cancer. Mammograms are available in 2D and 3D versions. A significant drawback of mammograms is limited soft tissue contrast. Specificity is also poor. Despite these disadvantages, mammograms remain a popular and low-cost screening tool for breast cancer.

A significant competitive advantage of MagSense technology is its ability to detect the smallest cancer tumors, thus allowing treatment to begin while the disease is still at an early stage. In addition, the MagSense system has performance and cost advantages that contribute to its overall value proposition. For example, although other medical imaging technologies can identify an area of interest, only MagSense technology has high specificity of detection, which minimizes the risk of false positives and unnecessary biopsy procedures. High levels of specificity are achieved through the use of cancer-targeting nanoparticles.

In addition, due to its very brief, low magnetic pulse, MagSense instruments are safer for patients, less costly to manufacture, and much less expensive for hospitals and clinics to install. No radiation or electro-magnetic shielding is required. Finally, one MagSense instrument can be used for many different diagnostic imaging tests. The versatility of the instrument improves ROI for hospitals and clinics.

Milestones

Imagion has received FDA feedback confirming its toxicology plan, general clinical study approach and that MagSense will be reviewed as a combination medical device.

Reports Progress on Regulatory Pathway

In April 2018, Imagion updated investors on its communications with FDA regarding its clinical development plan for MagSense technology. The FDA provided written feedback to a pre-submission document sent by Imagion earlier, confirming that: 1) the MagSense system is considered a combination medical product subject to review by the Center for Devices and Radiological Health (CDRH); 2) the Company's general toxicology plan is acceptable, based on the view that the nanoparticle formulation represents a low safety risk; and 3) the Company's clinical study approach is also acceptable, based upon sequential clinical studies beginning with a first-in-human early feasibility study.

Relocates US Operations to San Diego, California

In April 2018, Imagion relocated its US operations from New Mexico to San Diego, California. The move to San Diego capitalizes on that city's very active biotech community and facilitates Imagion's clinical progress by creating more opportunities for diagnostic and therapeutic collaborations. The Company expects to be fully operational in San Diego in the second quarter of 2018. The costs of the move are expected to be immaterial and neutral to 2018 spending.

Imagion raised A\$12 million through a 2017 IPO. Proceeds were used to fund A\$2.16 million of R&D spending, A\$1.08 million of professional fees and A\$3.13 million of employee costs and general expenses last year

Reports 2017 Financial Results

In March 2018, Imagion reported financial results for the year ended December 31, 2017. The Company reported 2017 revenues of A\$339,057 and a net loss of A\$7.8 million. The primary sources of revenues were interest income, sales of nanoparticles, a one-time grant from the state of New Mexico, and adjustments to the valuation of a derivative financial instrument. Imagion's principal uses of funds were research and development (A\$2.16 million), employee salary and expenses (A\$2.10 million), professional fees (A\$1.08 million) and general expenses (A\$1.03 million).

Recruits Dr. Farideh Bischoff as Vice-President, Clinical Research

In February 2018, Imagion hired Dr. Farideh Bischoff to lead the MagSense clinical program as Imagion's Vice-President of Clinical Research. Prior to joining Imagion, Dr. Bischoff helped lead development, regulatory submission and commercialization of molecular diagnostics at Biocept. She has also led numerous collaborative studies, including the NIFTY NIH Fetal Cell Study, composed of individuals from academic, pharmaceutical and biotech organizations. She holds a Ph.D. from the University of Texas, Graduate School of Biological Sciences.

Raises A\$12 million through Initial Public Offering

In June 2017, Imagion began trading on the Australian Securities Exchange under the symbol IBX. The Company raised A\$12 million through an Initial Public Offering of 60 million new shares priced at A\$0.20 per share. The IPO valued the Company at A\$43 million, post-listing.

Investment Risks

Technology risk

Developing diagnostic imaging tests for breast, ovarian, prostate and other cancers will require the availability and functionality of proven biomarkers for each type of cancer. There is no guarantee that a viable bio-marker will be available or functional for every application. In addition, adverse side-effects could be revealed from safety and toxicology studies. However, Imagion believes this risk is minimal since the biomarker concentrations it plans to use are orders of magnitude smaller than the therapeutic dosages that are already approved for use in humans. There is also risk that the sensitivity of MagSense technology will differ across applications, thus limiting the number of commercial applications for the technology.

Regulatory approval risk

There is risk that the FDA or regulatory agencies from other countries may choose to regulate the injectable nanoparticles as a drug, which would extend the timetable and increase the cost of securing regulatory approval. The Company plans to mitigate this risk by using cancer biomarkers that have already been cleared for human use. Another risk is that the FDA may alter its current stance and opt to require a PMA application for the MagSense instrument, which would require more and much larger clinical trials. Imagion's plan for limiting this risk is to secure regulatory clearance for the MagSense device first in Australia and use overseas approvals to create a pathway for a US regulatory submission.

Manufacturing risk

There is risk that transferring the nanoparticle formulation to an outside CMO will create delays or hurdles that slow Imagion's progress towards safety/toxicology studies and human clinical trials. In addition, while a firm has been hired to design the commercial instrument, progress may be slow, and the commercial instrument may prove more difficult or costly to manufacture than anticipated. Also, other companies in the medical imaging space are larger and better capitalized than Imagion and may develop alternative imaging platforms that erode the unique value proposition of MagSense technology. Increased competition could adversely affect Imagion's ability to commercialize its products.

Clinical study risk

Imagion plans to begin human clinical trials that will establish the efficacy and clinical utility of MagSense technology in HER2 breast cancer vis-à-vis the existing standard of care (i.e. mammograms and biopsies). While earlier studies have shown MagSense has superior sensitivity and detection capability, the possibility exists that results from human clinical trials may fall short of expectations. If that is the case, the value of Imagion shares could be negatively impacted.

Reimbursement risk

A key component of Imagion's business model is establishing MagSense technology as a new standard of care and obtaining reimbursement codes in single payer systems (Australia, Canada, the UK, etc.) and Medicare and insurance payer reimbursement in the US. One reason for human clinical studies is to gather data to support regulatory submissions and reimbursement codes. However, there is no guarantee that the Company's technology will be approved for reimbursement in any market. Also, a delay in securing reimbursement codes could slow the sales ramp-up for Imagion products.

Financing risk

Imagion will require significant amounts of additional capital to fund pivotal human clinical trials. The Company hopes to license its technology to a partner who will fund these trials. However, there is no guarantee that Imagion will be able to negotiate a licensing agreement or secure the necessary funding without a partner. Also, the

Imagion is commercializing a new, still unproven technology and must convince potential licensing partners, as well as physicians, hospitals, clinics and insurance companies of the superiority of its MagSense technology.

There is no guarantee that the successful results from pre-clinical studies can be replicated in humans.

possibility exists that the Company will burn cash faster than expected. Failure to obtain sufficient financing or control the cash burn rate could delay clinical trials and the commercialization of MagSense products.

Intellectual property risk

Imagion's commercial success depends on its ability to obtain patents and enforce and defend its intellectual property against third-party challengers. At present, the Company is not a party in any lawsuits, but future challenges to its patents cannot be ruled out. Defending a challenge to its patents would be both costly and time-consuming and Imagion may be at a disadvantage to a potential challenger because of limited financial resources.

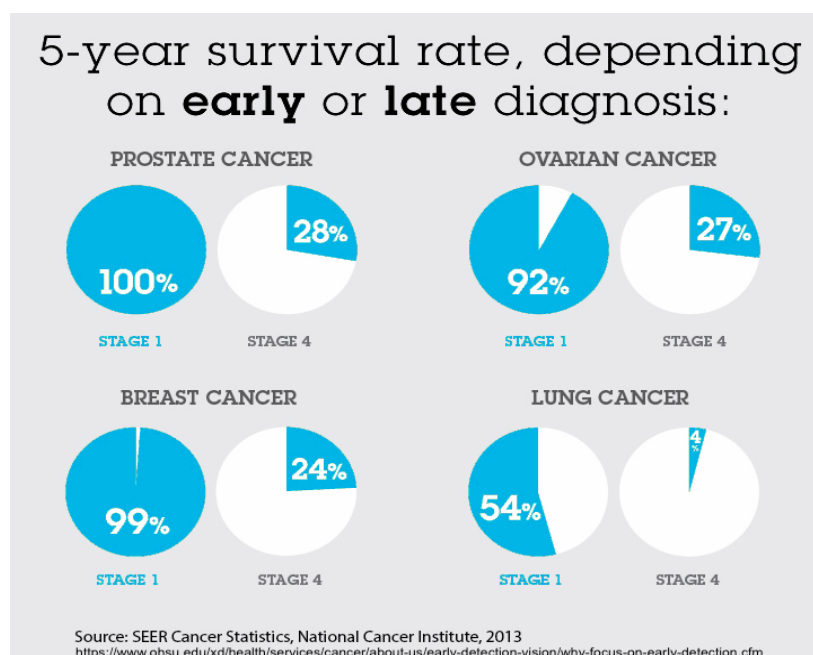
Summary

Imagion is developing and commercializing a new diagnostic imaging technology that has demonstrated superior sensitivity and detection capability when compared to the existing standards of care. The Company's MagSense technology addresses a large unmet medical need for a diagnostic imaging technology that can detect cancers at an earlier stage when therapy is most effective. In addition, unlike MRI, CT and PET, the MagSense device emits no radiation. As a result, the device is safer for patients, less expensive to manufacture and reduces capital expenditure and installation costs for hospitals and clinics.

Worldwide spending on diagnosing breast cancer may exceed \$20 billion in the next five years.

The market for cancer imaging diagnostics is enormous and growing. By 2020, worldwide diagnostic spending on breast cancer is predicted to exceed \$20 billion per year, spending on prostate cancer will exceed \$9.6 billion per year and diagnostic spending on ovarian cancer will reach \$7.2 billion per year, according to Transparency Market Research. Despite the enormous sums spent on diagnostics, cancer continues to be a leading cause of death worldwide due to too many cancers not being detected until late stages. The differences in outcomes for early detection versus late detection are enormous. For example, five-year survival rates for patients whose breast cancers are detected at Stage One are 99%, but survival rates drop to 24% for patients whose cancers are not detected until Stage Four. Similarly, five-year survival rates are 92% for ovarian cancers detected at Stage One but decline to 27% for cancers that go undetected until Stage Four. Clearly, a technology capable of detecting tumors at earlier stages could significantly improve patient outcomes and survival rates.

Graphic 6: Five-year Cancer Survival Rates



Pivotal human clinical trials of a MagSense test for staging HER2 breast cancer could begin in 2019.

Imagion has completed pre-clinical work on its diagnostic product for staging HER2 breast cancer and plans to commence safety/toxicology studies in Summer 2018, which will be followed by human feasibility studies. At the same time, the Company plans to begin conversations with potential licensing partners who could help it fund pivotal clinical trials, a regulatory submission and the commercial rollout of the technology. Pivotal human clinical trials could begin as early as 2019. Imagion anticipates launching its HER2 breast cancer product in the Australian market initially to take advantage of Australia's lower regulatory submission costs and single-payer healthcare

system. Commercialization in the Australian market will serve as a springboard for regulatory approvals and commercial sales in other single-payer markets (for example, Canada, the UK and the EU), eventually leading to a launch in the US market.

Imagion's goals over the next 12 months are to:

- ✓ Manufacture MagSense nanoparticles in sufficient quantities for clinical trials and develop a commercial version of the MagSense instrument;
- ✓ Complete safety and toxicology studies and advance the MagSense HER2 breast cancer product into human feasibility studies and pivotal human clinical trials;
- ✓ Negotiate a licensing agreement with an industry partner covering applications for MagSense technology in solid tumor cancers.

Financial Condition

Imagion's management expects internal spending in 2018 to be similar to 2017 spending, except for contracts and collaborations agreements to advance progress toward human clinical trials. Collaboration agreements cover the manufacturing of MagSense nanoparticles and the design and prototype production of a commercial version of the MagSense instrument.

Last year Imagion generated A\$339,057 in revenues and spent A\$7.8 million, which was slightly below the Company's earlier projections. Expenses consisted of A\$2.16 million in R&D spending, A\$2.1 million for employee salaries, A\$1.08 million for professional fees and A\$1.03 million of general expenses. Net losses totalled A\$7.73 million or roughly five cents per share, up from a loss of A\$581,109 one year earlier.

Imagion consumed A\$6.98 million in its operations last year paying suppliers, employees, and interest and financing costs on debt, invested A\$369,606 in property, plant and equipment, and generated A\$14,185,425 from financing activities. Sources of financing included A\$18.2 million from various share offerings and A\$294,544 from note issuance and other financings. These funds were used to repay A\$3.1 million of outstanding notes, cover A\$1.1 million of share issuance costs and repay A\$99,294 related to a lease. Imagion ended the year with A\$6.87 million of cash and equivalents on its balance sheet.

The Company anticipates raising A\$3.0 million to A\$5.0 million through a bridge financing this summer, which will help fund the ex-vivo feasibility study. Imagion expects to be able to leverage successful results from this study to negotiate a licensing agreement or return to the market for a more financing in 2019. Costs for pivotal clinical studies to support a regulatory submission are estimated at A\$5 million. The Company anticipates having negotiations underway with one or more licensing partners as it enters pivotal studies.

Revenue Opportunity for Breast, Ovarian and Prostate Cancer Products

The initial application for MagSense technology is staging HER2 breast cancer. The MagSense test will provide an alternative to lymph node biopsy. The Mayo Clinic estimates that approximately one of every five breast cancer patients have HER2 positive tumours. Worldwide, approximately 1.7 million new cases of breast cancer are diagnosed each year, which suggests an initial market in HER2 breast cancer valued at roughly \$51 million (20% of 1.7 million X \$1,500 per test). Longer-term, Imagion is working towards the development of a nanoparticle capable of identifying any invasive breast cancer, not just HER2 breast cancer. If these efforts are successful, the US market alone for applications in staging breast cancer could exceed \$2.4 billion

Imagion has cash of A\$5.87 million to fund 2018 operations. The Company plans to recruit a licensing partner to help fund pivotal human studies.

The potential market for a diagnostic tool that detects breast cancer at an earlier stage could exceed \$2.4 billion in the US and twice that amount worldwide.

(1.6 million breast cancer biopsies each year X \$1,500 per test). The worldwide market could easily be twice the size of the US market.

In ovarian cancer, the MagSense product will be offered as an alternative to transvaginal ultrasound, which is not sensitive enough to detect early-stage cancer. Patients found to have an elevated CA-125 blood test typically also undergo a transvaginal ultrasound, which is another tool for diagnosing ovarian cancer. If no cancer is detected, the patient will repeat the CA-125 blood test and transvaginal ultrasound at regular intervals. According to the World Cancer Research Fund International, approximately 239,000 new cases of ovarian cancer are diagnosed worldwide each year. Imagion plans to price the MagSense product for ovarian cancer at \$750 per test so the potential market for applications in ovarian cancer is likely to exceed \$17.9 million (239,000 cases per year X \$750 per test).

The potential market in prostate cancer is as large or larger than the breast cancer market. According to Globocan Cancer Facts, approximately 1.1 million new cases of prostate cancer are diagnosed worldwide each year. Therefore, the market for a MagSense product that stages prostate cancer and serves as a safer, less expensive alternative to a prostate biopsy could easily exceed \$2.3 billion (1.1 million cases X \$1,500 per test).

The revenue opportunity associated with a diagnostic imaging technology such as MagSense that is more sensitive than the existing standard of care and capable of detecting cancer at an earlier stage of the disease is significant. Imagion hopes to advance its first MagSense product, a test for staging HER2 breast cancer, into human clinical trials in 2019. Assuming these trials are successful, a regulatory submission and reimbursement code in Australia could soon follow, creating a pathway for regulatory submissions in other single-payor markets and eventually the US market. In addition, success in the initial breast cancer indication is likely to accelerate Imagion's clinical programs in other cancers. Because of the Company's printer/ink business model, a high percentage of Imagion's revenues would likely be recurring and rising exponentially as the installed instrument base grows. This in turn would facilitate the Company's transition to profitability and create extraordinary value for shareholders.

Income Statement

For the Fiscal Period Ending	12 months Dec-31-2014	12 months Dec-31-2015	Restated 12 months Dec-31-2016	12 months Dec-31-2017
Currency	AUD	AUD	AUD	AUD
Revenue	0.007	0.005	0.0	0.339
Other Revenue	-	-	-	-
Total Revenue	0.007	0.005	0.0	0.339
Cost Of Goods Sold	-	-	-	-
Gross Profit	0.007	0.005	0.0	0.339
Selling General & Admin Exp.	0.094	0.238	0.514	4.211
Stock-Based Compensation	-	-	-	0.624
R & D Exp.	2.436	3.761	6.025	2.156
Depreciation & Amort.	-	-	0.26	0.207
Other Operating Expense/(Income)	-	-	-	-
Other Operating Exp., Total	2.53	3.999	6.799	7.198
Operating Income	(2.523)	(3.994)	(6.799)	(6.859)
Interest Expense	(0.213)	(0.267)	-	(0.859)
Interest and Invest. Income	-	-	-	-
Net Interest Exp.	(0.213)	(0.267)	-	(0.859)
Currency Exchange Gains (Loss)	-	-	(4.311)	(0.001)
Other Non-Operating Inc. (Exp.)	-	-	(1.304)	(0.077)
EBT Excl. Unusual Items	(2.736)	(4.261)	(12.414)	(7.795)
Impairment of Goodwill	-	-	-	-
Other Unusual Items	-	-	-	-
EBT Incl. Unusual Items	(2.736)	(4.261)	(12.414)	(7.795)
Income Tax Expense	-	-	-	-
Earnings from Cont. Ops.	(2.736)	(4.261)	(12.414)	(7.795)
Earnings of Discontinued Ops.	-	-	-	-
Extraord. Item & Account. Change	-	-	-	-
Net Income to Company	(2.736)	(4.261)	(12.414)	(7.795)
Minority Int. in Earnings	-	-	-	-
Net Income	(2.736)	(4.261)	(12.414)	(7.795)
NI to Common Incl Extra Items	(2.736)	(4.261)	(12.414)	(7.795)
NI to Common Excl. Extra Items	(2.736)	(4.261)	(12.414)	(7.795)
Per Share Items				
Basic EPS	(3.34)	(5.2)	NA	(0.05)
Basic EPS Excl. Extra Items	(3.34)	(5.2)	NA	(0.05)
Weighted Avg. Basic Shares Out.	0.82	0.82	NA	153.836
Diluted EPS	(3.34)	(5.2)	NA	(0.05)
Diluted EPS Excl. Extra Items	(3.34)	(5.2)	NA	(0.05)
Weighted Avg. Diluted Shares Out.	0.82	0.82	NA	153.836
Normalized Basic EPS	(2.09)	(3.25)	NA	(0.03)
Normalized Diluted EPS	(2.09)	(3.25)	NA	(0.03)

Balance Sheet

Balance Sheet as of:	Dec-31-2014	Dec-31-2015	Restated Dec-31-2016	Dec-31-2017
Currency	AUD	AUD	AUD	AUD
ASSETS				
Cash and Equivalents	0.177	0.376	0.028	6.873
Total Cash & ST Investments	0.177	0.376	0.028	6.873
Accounts Receivable	-	-	-	0.009
Other Receivables	-	-	-	0.03
Total Receivables	-	-	-	0.039
Prepaid Exp.	-	-	0.009	0.341
Other Current Assets	-	-	-	0.017
Total Current Assets	0.177	0.376	0.037	7.269
Gross Property, Plant & Equipment	0.424	0.77	0.784	1.123
Accumulated Depreciation	(0.233)	(0.383)	(0.565)	(0.751)
Net Property, Plant & Equipment	0.191	0.387	0.218	0.372
Other Long-Term Assets	-	-	-	-
Total Assets	0.368	0.763	0.255	7.641
LIABILITIES				
Accounts Payable	0.132	0.153	0.867	0.402
Accrued Exp.	-	-	0.017	0.044
Short-term Borrowings	1.234	5.868	13.928	-
Curr. Port. of Cap. Leases	-	-	-	0.031
Other Current Liabilities	-	-	0.068	0.163
Total Current Liabilities	1.365	6.021	14.88	0.639
Long-Term Debt	3.324	3.324	-	-
Capital Leases	-	-	-	0.049
Other Non-Current Liabilities	-	-	-	-
Total Liabilities	4.689	9.345	14.88	0.689
Common Stock	0.08	0.08	0.0	28.687
Additional Paid in Capital	-	-	-	-
Retained Earnings	(4.401)	(8.662)	(15.078)	(22.873)
Treasury Stock	-	-	-	-
Comprehensive Inc. and Other	-	-	0.453	1.139
Total Common Equity	(4.321)	(8.582)	(14.625)	6.953
Total Equity	(4.321)	(8.582)	(14.625)	6.953
Total Liabilities and Equity	0.368	0.763	0.255	7.641

Cash Flow

For the Fiscal Period Ending	12 months Dec-31-2014	12 months Dec-31-2015	Restated 12 months Dec-31-2016	12 months Dec-31-2017
Currency	AUD	AUD	AUD	AUD
Net Income	(2.736)	(4.261)	(12.414)	(7.795)
Depreciation & Amort.	0.052	0.15	0.26	0.207
Depreciation & Amort., Total	0.052	0.15	0.26	0.207
Asset Writedown & Restructuring Costs	-	-	(1.495)	(0.128)
Stock-Based Compensation	-	-	-	0.624
Other Operating Activities	-	-	6.693	0.859
Change in Acc. Receivable	-	-	-	(0.066)
Change in Acc. Payable	0.065	0.089	3.86	(0.364)
Change in Other Net Operating Assets	(0.025)	(0.068)	(0.111)	(0.314)
Cash from Ops.	(2.644)	(4.09)	(3.207)	(6.977)
Capital Expenditure	(0.048)	(0.346)	-	(0.37)
Cash Acquisitions	-	-	-	-
Divestitures	-	-	-	-
Invest. in Marketable & Equity Securt.	-	-	-	-
Net (Inc.) Dec. in Loans Originated/Sold	-	-	-	-
Other Investing Activities	-	-	-	-
Cash from Investing	(0.048)	(0.346)	-	(0.37)
Short Term Debt Issued	1.036	4.635	-	0.081
Long-Term Debt Issued	1.33	-	-	0.213
Total Debt Issued	2.365	4.635	2.778	0.295
Short Term Debt Repaid	-	-	-	(3.109)
Long-Term Debt Repaid	-	-	-	(0.099)
Total Debt Repaid	-	-	-	(3.208)
Issuance of Common Stock	-	-	-	18.208
Total Dividends Paid	-	-	-	-
Special Dividend Paid	-	-	-	-
Other Financing Activities	-	-	-	(1.109)
Cash from Financing	2.365	4.635	2.778	14.185
Foreign Exchange Rate Adj.	-	-	(0.2)	0.007
Misc. Cash Flow Adj.	-	-	0.961	-
Net Change in Cash	(0.327)	0.199	0.332	6.845

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