Zacks Small-Cap Research

March 25, 2014

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FluoroPharma Md (FPMI-OTCBB)

FPMI: CardioPET Data Provide Early Glimpse of High Performance

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	11/17/2012
Current Price (03/24/14)	$0.67
Target Price	**$2.15**

OUTLOOK

FPMI is looking to capitalize on the rapid growth of PET in cardiac diagnostics. In development are three novel cardiac PET radiopharmaceuticals, two of which could possibly launch within the next two to three years. Data and images from ongoing looks highly promising. Current PET tracers suffer from high cost, safety issues and availability shortages, affording considerable demand for novel radiopharmaceuticals such as FPMI's agents. Company is led by highly qualified management which has done a commendable job with minimizing cash burn while making progress on product development. However, being a development-stage company, an investment in FPMI comes with inherent meaningful risk.

We are maintaining our Outperform rating.

SUMMARY DATA

52-Week High	**$0.84**
52-Week Low	**$0.47**
One-Year Return (%)	**-15.53**
Beta	**-0.20**
Average Daily Volume (sh)	**270,179**
Shares Outstanding (mil)	**26**
Market Capitalization ($mil)	**$18**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**N/A**
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 2014 Estimate	**N/A**
P/E using 2015 Estimate	**N/A**
Zacks Rank	**N/A**

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

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2014	0.0 E	0.0 E	0.0 E	0.0 E	0.0 E
2015					0.0 E
2016					0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.04 A	-$0.05 A	-$0.10 A	-$0.11 A	-$0.30 A
2014	-$0.07 E	-$0.06 E	-$0.08 E	-$0.09 E	-$0.30 E
2015					-$0.25 E
2015					-$0.21 E

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

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WHAT'S NEW…

2013 10-K Filed

FluoroPharma filed their 10-K for the year ending December 31, 2013. While SG&A came in about $200k higher than our estimate, much of the difference was from (non-cash and non-recurring) loss from asset sales. The difference in SG&A was also more than offset by lower than modeled R&D expense. The net result is operating expenses remaining within our expectations. The company also continues to keep cash burn in check and in gaining the attention of institutional life sciences investors, has demonstrated the ability to attract high quality financing. Most importantly, the company continues to make meaningful progress with clinical studies of CardioPET and BFPET which has included the recent announcement and presentation of compelling data and images from the phase II trial of CardioPET.

Q4 operating expenses were $1.3M, about $200k higher than Q3 but slightly lower than our $1.2M estimate. We continue to expect operating expenses to increase with clinical trials progression. Q4 net loss to common and EPS were $2.6 million and ($0.11) but excluding $818k non-cash loss on the sale of trading securities (FPMI sold NAVB stock at a loss during Q4) and $161k non-cash loss on revaluation of derivative liabilities (related to change in value of warrants issued with preferred stock), net loss to common and EPS were approximately $1.6 million and ($0.07), compared to our $1.6 million loss and ($0.06) estimates.

Cash used in operating activities was $1.3M in Q4 up from an average of $667k in the first three quarters of the year. Ex-changes in working capital, cash used in operating activities in Q4 was $1.1M, up from an average of $800k in the first three quarters of the year. Cash burn averaged about $830k/quarter in 2013, roughly flat from 2012.

FPMI exited 2013 with $1.1M in cash and equivalents plus $635k in tradable securities (NAVB common stock acquired via the Q3 preferred stock sale). Subsequent to quarter end, FPMI raised an additional $235k (gross) from the sale of common shares.

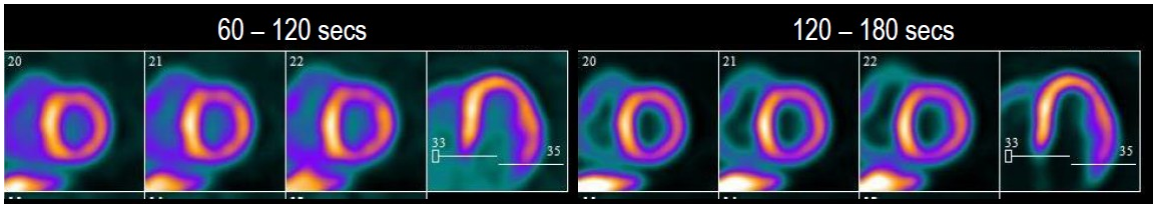
Promising Phase II Data Reinforces Our Confidence in CardioPET
Data and images from FluoroPharma's ongoing phase II trial of its novel imaging agent, CardioPET, were presented in early February 2014 at the Society of Nuclear Medicine and Molecular Imaging Meeting in Palm Springs, CA.

As a reminder, CardioPET is being developed as a PET imaging agent to better diagnose acute and chronic coronary artery disease (CAD) in patients that cannot undergo stress testing, among other potential indications. The Belgian-based phase II trial is an open label study designed to assess safety and performance of CardioPET compared to SPECT myocardial perfusion imaging (MPI) agents and angiography.

The study's focus is assessment of both myocardial perfusion and myocardial fatty acid uptake. The data presented in February relate to assessment of the safety of CardioPET, image quality and in determination of the optimal timing for PET imaging after injection. Future data from the study will compare results to that of SPECT myocardial perfusion imaging agents.

Fifteen patients with known or suspected coronary artery disease were included in the analysis. Images were taken in three to five minute durations at intervals of one to ten minutes and at 15, 30, 45 and 55 minutes after injection. Image quality was graded as either optimal, sub-optimal or non-interpretable. Changes in blood pool activity, liver activity and delineation defects over time were recorded.

Relative to safety, there were no adverse events and no other safety issues related to CardioPET (one patient had a panic attack from being in the imaging system). Relative to quality of the images and performance of CardioPET, images at all time points from three minutes following injection were considered excellent. Blood pool activity began to decline in the initial one to three minute timeframe and blood pool clearance was totally completed in all patients at five minutes (image below). Rapid blood pool clearance is beneficial as it allows for imaging shortly following injection and reduces patient exposure to imaging radiation.



CardioPET enters the myocardium similar to the way of fatty acids and remains there long enough to allow for PET imaging. The images also showed that fatty acid uptake decreased over time. In ischemic heart conditions, uptake of fatty acids is reduced, which would be expected in these patients.

The interim data, image quality and safety were considered very promising. The ability to attain high quality images very shortly after injection is of particularly benefit and significant. We expect there will be additional data and images presented in the near-term and expect similarly positive results. This interim data reinforces our belief that CardioPET has potential to unseat the current standard imaging agents for coronary artery disease imaging, particularly for those patients unable to undergo stress testing.

Industry Veteran Hired to Lead Commercialization Strategy, Board of Directors Beefed Up

In late October 2013 FPMI announced that they brought on Edward Lyons to fill the newly created position of V.P. of Marketing. He comes with an impressive background which presumably offers FPMI potentially valuable industry contacts as well as significant operational and product specific knowledge. Mr. Lyons, who was with GE Healthcare as that company's Global Marketing Director, Nuclear Medicine, will head FPMI's marketing and commercialization strategy. Mr. Lyons comes with a vast background in diagnostic imaging including positions with Bristol-Myers and DuPont Pharmaceuticals and culminating with the high-level position at advanced imaging giant, GE Healthcare. FPMI's press release also notes that Mr. Lyons was Chief Technologist in Nuclear Medicine and Nuclear Cardiology at Philadelphia Hear Institute and Temple University Hospital.

In March 2014 FPMI announced that they added Andrew Sassine to their Board of Directors. Mr. Sassine's background includes 13 years at Fidelity Investments working as a research analyst and managing several of the company's small cap funds. He also serves on the boards of several other life sciences companies.

Product Development Progress

Although development timelines slipped during 2013 as FPMI needed to raise additional capital, the company has made significant progress on moving both CardioPET and BFPET through the development pipeline. The capital infusion in Q3 allowed the company to dedicate more resources towards the ongoing phase II study of CardioPET and should facilitate enrollment of BFPET studies, slated to begin at Massachusetts General Hospital.

As noted above, we expect additional data coming out of the CardioPET studies in the near-term. BFPET studies had been expected to commence enrollment by the end of 2013. That was delayed but we think that will happen by mid-year 2014.

CardioPET data to-date has been consistently very positive and our expectations that follow-on results, which we think will be upcoming, will be similarly positive. The Belgian-based phase II trial is an open label study designed to assess safety and performance of CardioPET compared to SPECT myocardial perfusion imaging (MPI) agents and angiography. As a reminder, on in late February 2013 FPMI announced that the initial images from the phase II trial "show high resolution in the heart and provides extremely clear image quality". Then in June the company announced that an internal review of additional data from this study supported earlier findings of excellent image quality. While FPMI did not provide specifics on the images in the June press release, Dr. Manual Cerqueira, Chairman of the Department of Nuclear Medicine at the Cleveland Clinic was quoted and noted, "The images thus far obtained from CardioPET indicate excellent image quality. The immediate acquisition of images will be very efficient for patient work flow." The interim data, which was finally revealed (as discussed above) in early February 2014 at the Society of Nuclear Medicine and Molecular Imaging Meeting in Palm Springs, did not disappoint and provided the most substantive evidence to-date of the potential performance benefits of CardioPET over current standard imaging agents.

Relative to BFPET, in January 2013 FPMI announced that phase II trials will be conducted at Massachusetts General Hospital. Similar to the investigator-led study, the phase II study will compare BFPET to Rb-82 and/or

traditional SPECT agents such as sestamibi which suffer from certain drawbacks such as high cost or comparably (relative to BFPET) lower image quality.

As a reminder, in July and November 2012 FPMI announced image results from a 20-patient investigator-sponsored clinical trial conducted in China where patients with CAD were imaged using BFPET.

Alan Fishman, principal investigator of the BFPET phase I trial (completed in 2008), commented on the initial results of the China-based study released in July, noting that the "initial results are impressive. Image quality obtained using PET is superb. BFPET shows clear diagnostic qualities as well as increased resolution, inherent in PET. The initial images look spectacular and we are confident that when all the patients are imaged, the data will further support clinical development of the agent." His confidence was further bolstered when additional data was available in November, noting "We saw a high level of agreement between the angiography, the SPECT and the BFPET images. These additional images demonstrate that BFPET shows clear diagnostic qualities as well as the increased resolution, inherent in PET."

As highlighted in the images below, image quality with BFPET as compared to standard imaging agents appears to be excellent.

Difference In Image Quality Is Obvious Even To The Untrained Eye

Image Using Sestamibi

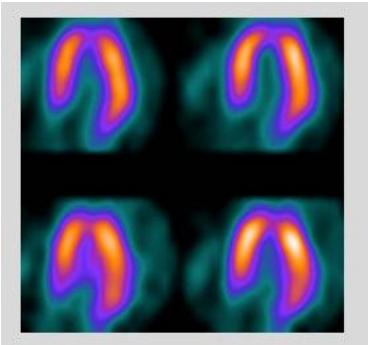
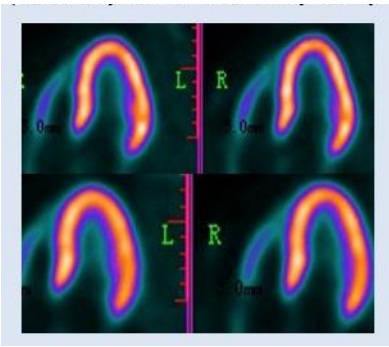


Image Using BFPET



While we had expected this phase II BFPET study at Mass General to initiate by year-end 2013, this was delayed, likely due at least in part to the need to raise additional capital. With additional funds from the Q3 financing, we now expect enrollment in commence during the first half of 2014. The delay has pushed back our modeled launch projections of BFPET by 6 – 12 months and we now think the product may not reach the commercial market until 2017 or 2018.

Industry Report: PET To Grow 20% Through 2021 Driven In Part By Cardiology

By just about all accounts, sales of PET scanners and PET radiopharmaceuticals and PET procedural volumes are expected to grow at a significant rate over the next several years. This is a result of a number of factors including; PET's excellent image quality (particularly as compared to SPECT), greater availability of PET scanners, new applications for the use of PET in various specialties, an increasing focus on earlier intervention and personalized medicine and higher reimbursement (particularly as compared to PET).

An industry report by Bio-Tech Systems was published in early August 2013 and provides updated estimates for the growth of PET and SPECT. Of particular interest in the report in relation to FPMI's products are:

> While SPECT sales are forecast to grow at a CAGR of 10%-12% to $1.7 billion through 2021, PET is expected to grow at a CAGR of 20% to $4.7 billion through the same period. Bio-Tech Systems notes, "This will stimulate more research and investment adding strength and stability to venture companies as well as those more established in the field."

> Cardiac PET is expected to be a high growth area. Bio-Tech Systems notes,

<> "PET cardiology will also benefit by an influx of new products for imaging myocardial perfusion and viability, allowing more effective treatment."

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> Alzeheimer's disease is also expected to be a catalyst to growth of PET through imaging of amyloid plaques. FPMI's AZPET is in early development stage for directly imaging amyloid plaques which may then aid physicians in providing more directed treatment through personalized medicine. Bio-Tech expects PET radiopharmaceuticals to gain more acceptance in the near term fueled by the increasing acceptance of between imaging and therapy.

> The report also mentions that new oncology radiopharmaceuticals should help fuel growth of both PET and SPECT. Oncology could be a specialty that FPMI looks to enter in the future. In March 2013 the company announced it received a patent covering metabolic markers for PET and SPECT, specific use for which includes tumor tissue activity.

Heart Disease Trends Continue to Favor FPMI

Trends in heart disease are one of the most reported on statistics in health care due in large part to the pervasiveness of the problem, particularly in the U.S. Many of the major private and public health organizations provide historical as well as projected figures on the proportion of a given population estimated to have heart disease and/or be at-risk.

FPMI's March 2013 investor presentation cites the Heart Disease and Stroke Statistical Update, which is one of the most widely recognized ongoing research pieces on the epidemic which is put together by the American Heart Association (AHA), the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH). The theme of the reports make it clear that heart disease is a problem that will not be going away anytime soon. The report notes that while death rates from cardiovascular disease have declined, the burden remains high with coronary heart disease causing about 1 in every 6 deaths. Risk factors such as hypertension (~35% of U.S. adults), smoking (23% of men, 18% of women), high cholesterol (15% of U.S. adults), and obesity (67% either overweight or obese) remain significant problems.

Other, less recognized studies, also clearly point heart disease as a long-term problem. For example, *F as in Fat: How Obesity Threatens America's Future 2012*, a report by Trust for America's Health and the Robert Wood Johnson Foundation forecasts adult obesity rates and the likely resulting rise in obesity-related disease rates for each state through to the year 2030. The study notes that, " If obesity rates continue on their current trajectories, by 2030, 13 states could have adult obesity rates above 60 percent, 39 states could have rates above 50 percent, and all 50 states could have rates above 44 percent." Relative to what this could mean for obesity-related diseases, the study notes, "If states' obesity rates continue on their current trajectories, the number of new cases of type 2 diabetes, coronary heart disease and stroke, hypertension and arthritis could increase 10 times between 2010 and 2020—and double again by 2030."

While all of these statistics point to a potentially huge long-term problem for the U.S. healthcare system, it is a problem that FPMI directly addresses and which the company will potentially capitalize on following the launch of their first novel molecular imaging agent - which we think could happen in 2016 or 2017.

BUSINESS

FluoroPharma Medical, Inc. ("FluoroPharma") seeks to develop breakthrough molecular imaging agents for positron emission tomography (PET) to fulfill critical medical needs. The company's products are designed to improve patient diagnosis and management by evaluating various forms of cardiac disease at the cellular and molecular level. Each year, millions of patients undergo molecular imaging studies in the U.S. The main reason for these studies is to detect and evaluate ischemic heart disease and myocardial infarction (MI) in patients with acute and chronic forms of coronary artery disease (CAD). These images provide benefit in the initial evaluation of patients with suspected but unproven CAD, and in those patients in whom a diagnosis of CAD has been established and information on prognosis or risk is required.

FluoroPharma's current focus is on three separate cardiac molecular imaging pharmaceuticals, two of which are in clinical-stage and recently entered phase II clinical trials. The third candidate is still in early development stage with initial clinical testing still likely to be years away. If all goes to plan, the first of the three products could be on the U.S. market within the next two to three years. FluoroPharma's products are aimed at improving overall patient care via improved disease detection and are expected to; provide significantly greater diagnostic accuracy compared to currently employed nuclear imaging agents and modalities, increase the use of PET in cardiac imaging, and help reduce the number of unnecessary diagnostic and therapeutic procedures.

In the U.S., there are an estimated 12 million PET imaging procedures done per year - however, the vast majority of these scans are for the diagnosis of cancer. While PET is becoming more established in the cardiac setting, this segment continues to be dominated by lower cost competing modalities. By all accounts, this is quickly changing as several factors have led to a shift in favor of PET for the diagnosis of cardiac disease. FluoroPharma expects to capitalize on this growth through the introduction of novel cardiac PET tracing agents, the market for which is expected to grow by at least 14% annually over the next four years to approximately $900 million (or more). Aside from one currently marketed branded cardiac PET tracer (which suffers from certain issues), the market is largely is wide open.

CARDIAC DISEASE

Roughly one-third of all Americans are estimated to have some form of cardiovascular disease, with approximately 13 million people suffering from coronary artery disease. Cardiovascular disease is the number one leading cause of death in the U.S., claiming almost one million lives per year. People with cardiovascular disease typically have an accumulation of plaque within the walls of the coronary arteries (i.e. - atherosclerosis) that supply the myocardium (heart muscle) with oxygen. Known as coronary artery disease (CAD), the condition is progressive and can result in severely reduced supply of blood to the heart (i.e. - myocardial ischemia or ischemic heart disease). Acute coronary syndrome (ACS) is a term used to describe symptoms of the disease, such as chest pain or a heart attack. As these symptoms may not be present until the disease has progressed to an advanced stage, barring a reliable diagnosis and appropriate intervention, CAD is often fatal. Cardiac imaging is used to diagnose CAD and to determine the presence and severity of ischemic heart disease and the related risk of suffering a heart attack. It is also used to help determine the most appropriate course of treatment.

Evaluation of CAD…

For lower to moderate-risk patients, an **exercise stress test** may be used to measure heart function. As the name implies, the test measures the heart's ability to respond to external stress. In an exercise stress test, the patient is hooked up to an EKG while he uses a treadmill or stationary bike. Coronary circulation is measured and compared to when the heart is at rest. While exercise stress tests are generally considered to have some utility in assessing the patient's general physical condition and in the diagnosis of ischemic heart disease, the test suffers from relatively low accuracy and is even less reliable in assessing atherosclerosis or for evaluating the patient's risk of suffering a heart attack. It also can not detect vulnerable plaques - which are particularly prone to causing heart attacks (FluoroPharma's VasoPET agent is being designed to be able to identify vulnerable plaques). As a result of its significant limitations, an exercise stress test is often used with patients that present with only low-to-moderate risk symptoms (i.e. - history of smoking, heart disease, heart attack, diabetes, high blood pressure, etc.).

Exercise Stress Test



SOURCE: wikipedia.com

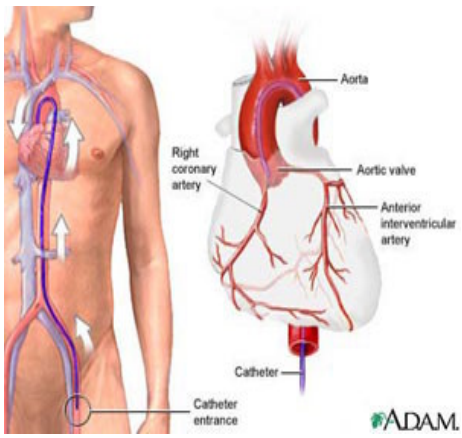
For moderate-to-severe risk individuals and those where cardiac stress tests are insufficient or otherwise not appropriate (i.e. - when stressing the heart may be deemed too dangerous), physicians will often use **non-invasive imaging** (i.e. - PET, SPECT, MRI, CT, ultrasound) as the initial tool for the diagnosis of CAD. Where appropriate, non-invasive imaging can also be used in combination with a stress test where the heart is stressed either through exercise or drug stimulation. FluoroPharma's BFPET agent is designed to be used in conjunction with stress

testing, while their CardioPET product is designed to be used with patients that can not undergo stress testing. We discuss the various imaging modalities in greater detail later in this report.

Coronary

Angiogram

If non-invasive imaging fails to provide a definitive diagnosis, **coronary angiogram** can be performed. Coronary angiograms are invasive procedures that involve the insertion of a guide wire into the femoral (leg) artery which is threaded up to the aorta. A catheter is then inserted along the wire and a contrast agent injected into the bloodstream - the contrast agent helps to highlight areas of arterial narrowing with an X-ray. Patients diagnosed with severe atherosclerosis may then undergo **revascularization** in order to clear and re-open the arteries. Revascularization is not only highly-invasive, at about $40k per procedure, it is also costly. PET (FluoroPharma's target market), when used in place of SPECT (the current dominant cardiac imaging modality), has been shown to reduce the number of coronary angiography and revascularization procedures by over 50% and reduce overall costs by 30% (see Appendix). FluoroPharma's CardioPET agent is being developed to help more accurately identify patients that will benefit from revascularization.



SOURCE: adameducation.com

CARDIAC IMAGING

Within cardiac imaging there are several different modalities including ultrasound, MRI, PET, computer tomography angiograph (CTA or CT) and single-photon emission computed tomography (SPECT). PET and SPECT are nuclear (also called molecular) imaging modalities which provide the highest level of detail relative to organic anatomic changes (i.e. - function and metabolism) in the body while the others primarily only provide information about the anatomy and structure of the body. CT and MRI, while sometimes used as an adjunct to PET and SPECT for cardiac imaging, have not gained widespread acceptance as a first-line diagnostic for this application and are generally viewed as complementary to molecular cardiac imaging. This is especially the case for myocardial perfusion imaging (MPI) which is used to determine the volume of blood flow to the heart and the function of the heart muscle. **CT coronary angiography**, which uses a high speed (64-slice) CT camera and drugs to slow the heart, is a relatively new procedure and provides more functional detail of the coronary arteries than conventional CT scans. Although CT coronary angiography is gaining greater acceptance in the diagnosis of CAD, MPI via nuclear imaging remains the most definitive non-invasive technique for diagnosing CAD. As PET and SPECT are considered the gold-standards for high accuracy cardiac imaging, we confine our discussion solely to these two imaging modalities.

Nuclear/Molecular Imaging

Nuclear imaging uses radioactive materials called radiopharmaceuticals or radiotracers which are injected into the patient and accumulate in the area of the body to be imaged. These tracers emit very minute levels of radioactivity which are detected by a camera (i.e. - PET, SPECT) which can then provide very detailed molecular images.

PET

Scanner

PET and SPECT are the two most widely used nuclear imaging modalities. SPECT has some utility in a number of applications including neurology and oncology but is primarily used in cardiology. In cardiac scans, PET has been shown to provide a better picture of blood flow compared to SPECT which allows it to better identify those patients that should undergo revascularization and reduce reliance on coronary angiography as a definitive diagnostic. Another significant differentiator is that PET scans are quantifiable, while SPECT scans are not - the difference is important as approximately 20% of CAD patients have global ischemia as a result of multi-vessel CAD which can not be detected by SPECT but can be with PET due to its

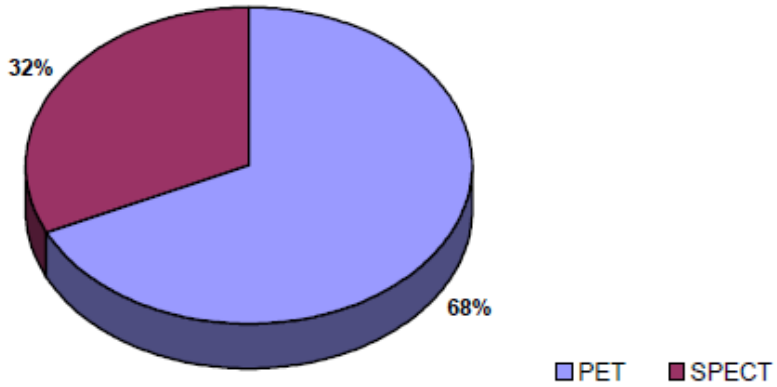


quantifiable functionality. PET's superior sensitivity has been documented in clinical studies and was even more apparent with heavier and large-breasted patients. PET uses different types of
SOURCE:www.medicalcityhospital.com radiopharmaceuticals compared to SPECT, which contributes to the greater sensitivity of PET.

Despite the greater accuracy afforded by PET, nuclear imaging is currently dominated by SPECT, accounting for approximately 90% of all nuclear scans. In aggregate, molecular imaging is used in approximately 10 million MPI scans every year in the U.S. Estimates put the number of SPECT cameras currently in use at about 14k, compared to just 140 dedicated PET systems being used for cardiac applications. The dominance of SPECT up to now has to do with its lower cost and, until recently, more favorable insurance reimbursement. In addition, PET has historically been limited to only a few PET centers and used primarily for oncology.

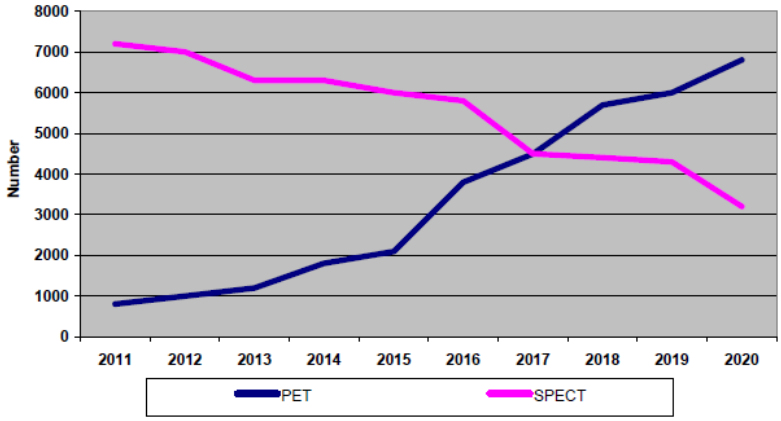
The tides are turning however, with rapid growth in the number of dedicated PET centers and technological advancements making PET scanners even more sensitive and providing greater image uniformity (especially as compared to SPECT). The increased adoption of PET over SPECT in cardiology has also been facilitated by the introduction of lower cost PET scanners, coupled with significantly higher reimbursement compared to SPECT - which makes the economics of owning a PET scanner much more palatable for imaging facilities than they might have been previously. An opportunity to increase PET scanner utilization beyond oncology into applications such as cardiology is viewed highly attractive to health care providers which are looking to cover the relatively high fixed cost of their nuclear scanners (compared to a relatively low per-scan, variable cost). This, along with a global shortage of molybdenum-99 (used for SPECT imaging), has helped to significantly increase the use of PET, especially as a first-line diagnostic for cardiac procedures. In fact, The American College of Cardiology Environmental Scanning Report 2011 notes, "A greater use of PET can be expected for both assessing blood flow quantitatively and molecular imaging of atherosclerotic plaques and myocardial disease states." The expected transition away from SPECT to PET for cardiac imaging is echoed by a May 2011 molecular cardiac imaging industry report by TriMark Publications titled *Nuclear CardiologyMarkets;Trends, Industry Participants, Product Overviews and Market Drivers* which notes, "A continued movement towards PET from SPECT will result in a nearly 50% of the entire cardiac SPECT market transitioning to PET within the next decade, resulting in a total SPECT decline from over 90% of the nuclear medicine studies to 68%."

Projected Market Share of PET and SPECT in 2020



SOURCE: TriMark Publications, May 2011 *Nuclear CardiologyMarkets;Trends, Industry Participants, Product Overviews and Market Drivers.* PlanClear Company "Quarterly Update 2010".

Projected Growth Rate of PET and SPECT Cameras



SOURCE: TriMark Publications, May 2011 *Nuclear CardiologyMarkets;Trends, Industry Participants, Product Overviews and Market Drivers.* PlanClear Company "Quarterly Update 2010".

Bio-Tech Systems, a healthcare market research firm specializing in medical imaging, also supports the expectation of more rapid growth of PET compared to SPECT. In August 2013 they published their most recent PET/SPECT industry forecast noting that while SPECT sales are forecast to grow at a CAGR of 10%-12% to $1.7 billion through 2021, PET is expected to grow at a CAGR of 20% to $4.7 billion through the same period.

Bio-Tech Systems points to a number of factors to drive PET growth including; PET's excellent image quality (particularly as compared to SPECT), greater availability of PET scanners, new applications for the use of PET in various specialties, an increasing focus on earlier intervention and personalized medicine and higher reimbursement (particularly as compared to PET).

Of particular interest in the report in relation to FPMI's products are:

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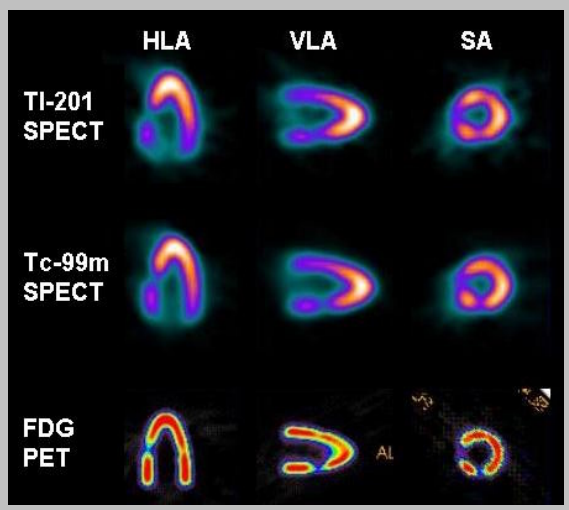
SPECT vs. PET Cardiac Images

The images below are from a paper entitled *PET Myocardial Perfusion Imaging*, by Dr. Josef Machac in which he compares the clarity, functionality and usability of cardiac images produced by SPECT versus those from PET. Dr. Machac is the director of Nuclear Medicine at The Mount Sinai School of Medicine of New York University. His conclusion (verbatim below) is that PET provides better clarity, uniformity and usability compared to SPECT.



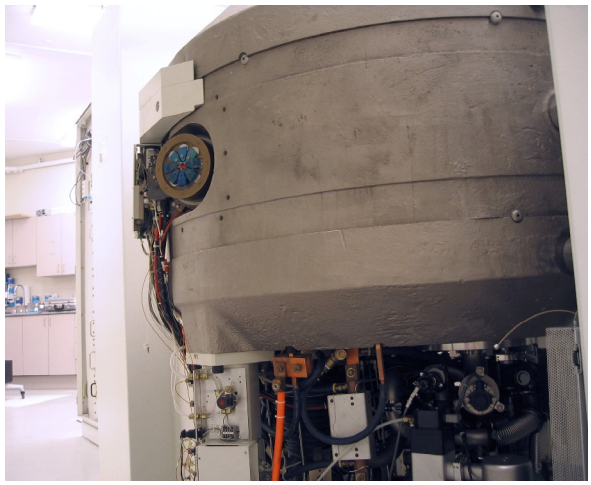
Dr. Josef Machac, *PET Myocardial Perfusion Imaging*: Image uniformity is by far the most important property of PET imaging for cardiac imaging. Coincidence detection allows more effective correction for non-uniform attenuation than for SPECT imaging. Non-uniform attenuation in the chest results in multiple different patterns of SPECT images attenuation, depending on body habitus and position of the heart. Current attenuation correction hardware and software algorithms for SPECT imaging have come a long way in improved effectiveness but offer only a partial correction of the problem, and sometimes result in greater error. Furthermore, most SPECT cardiac acquisition is performed over 180 degrees over the chest, which results in additional spatial distortion and non-uniformity. The images (above) are from a cardiac phantom, filled with either Tl-201, Tc-99m, acquired with a SPECT imaging system, or F-18 FDG acquired with a PET scanner, immersed in a water bath, containing defects of varying sizes. In the SPECT images, we see progressive attenuation toward the base. Experienced readers are familiar with this pattern and learn to distinguish this pattern from a real defect, also seen in the image. Sometimes, due to non-uniform attenuation, this is difficult to do. A real perfusion defect may be exaggerated in size and severity. On the other hand, a real perfusion defect can be hidden within an area of apparent attenuation. PET imaging, utilizing a transmission scan in addition to the emission scan, corrects this problem, as seen in the images above.

PET Radiopharmaceuticals

Radiopharmaceuticals consist of compounds made up of radionuclides which are combined either with substances normally found in the body such as glucose, water, or chloride or into molecules that bind to receptors in the body. Certain radiopharmaceuticals may be preferable depending on the part of the body or type of tissue being studied (i.e. - cancerous tumors, brain, heart, etc.). Radionuclides undergo radioactive decay immediately following its production - the energy emitted as they decay is detected by the imaging camera. This decay (measured in half-lives), depending on the radionuclide, can be very rapid. In general, PET radionuclides have significantly shorter half-lives than those used in SPECT and most PET radionuclides must be produced in a cyclotron - which is a particle accelerator and typically too cost prohibitive for an imaging center to build or own. Radionuclides with very short half-lives and which must be produced in a cyclotron can severely limit or altogether prohibit their commercial use.

www.ottawaheart.com

Cyclotron



SOURCE:

The typical radiopharmaceuticals used for PET perfusion imaging are N-13 ammonia (10 minute half-life), oxygen-15 water (2 minute half-life), rubidium-82 (75 second half-life), and fluorine-18 (110 minute half-life). N-13, oxygen-15 water, and fluorine-18 all must be produced from a cyclotron. **N-13 ammonia** is primarily used only in research applications while **oxygen-15 water**, with a very short half-life and a poor contrast between blood flow and the myocardium, have precluded its widespread use. **Rubidium-82** (R-82) is produced from a commercially available strontium-82 (S-82) generator - which is a portable canister containing S-82. S-82 decays to R-82 and has a significantly longer half-life (28 days) which allows imaging centers to have R-82 on-site. While R-82 is practical for commercial use from a quality-of-image and half-life standpoints, the generators themselves are relatively expensive (~ $30k - $40k per month), - which can limit its use. CardioGen-82, an Rb-82 generator-based tracer marketed by Bracco Diagnostics Inc., currently dominates PET cardiac imaging and is the only FDA-approved generator-based tracer that is reimbursed for PET MPI. **Fluorine-18** (F-18) is synthesized into fluorodeoxyglucose (FDG), which is the most commonly used PET radiopharmaceutical - its use, however, is primarily in oncology. FluoroPharma, along with other companies, are developing FDG-based radiopharmaceuticals specifically for cardiac applications. FlouroPharma's BFPET and CardioPET are both FDG-based tracers.

SPECT radiopharmaceuticals are different from those employed with PET. As FluoroPharma's target market is PET, we confine our discussion of SPECT radiopharmaceuticals to a description of the common cardiac tracers. The most commonly commercially employed cardiac SPECT radioisotope is technetium-99 (produced in a molybdenum generator). Thallium-201, is also used in certain settings. The market for branded SPECT radiopharmaceuticals is highly concentrated between just a few companies. Lantheus Imaging makes a technetium-99 based SPECT cardiac tracer called Cardiolite which is the leading cardiac perfusion agent. GE Healthcare also makes a technetium-99 based agent, named Myoview. Lantheus' T-201 thallium-based agent had been considered the SPECT MPI gold-standard prior to the introduction of Cardiolite.

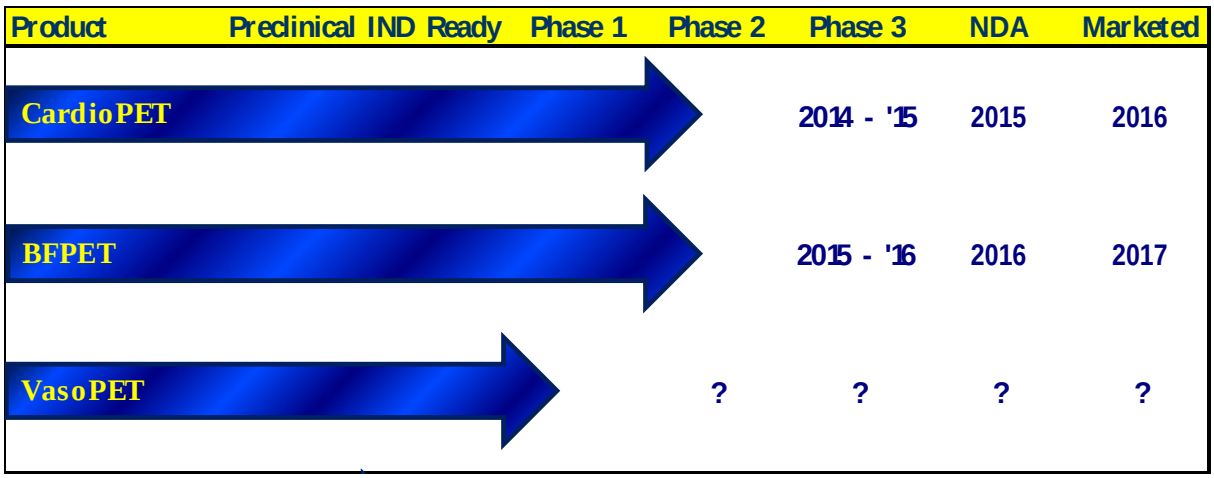
PRODUCTS

FluoroPharma's current focus is on three separate cardiac molecular imaging pharmaceuticals, two of which (CardioPET and BFPET) are in clinical-stage and recently entered phase II trials. The third candidate (VasoPET) is still in early development stage with initial clinical testing still likely to be years away (FPMI recently indicated that due to its limited patent life – U.S. patent expires in 2016 – that they may decide to not pursue further development of VasoPET). If all goes to plan, the first of the three products could be on the U.S. market within the next two to three years. FluoroPharma's products are aimed at improving overall patient care via improved disease detection and help better guide appropriate treatment. FluoroPharma's PET agents are expected to; provide significantly greater diagnostic accuracy compared to currently employed nuclear imaging agents and modalities, increase the use of PET in cardiac imaging, and help reduce the number of unnecessary diagnostic and therapeutic procedures.

FluoroPharma obtained the licenses to the patents (composition of matter and some method of use patents) of the proprietary technology and indications related to their products from the Massachusetts General Hospital MGH). There are currently four patents issued and seven patent applications pending. Any future patent applications are expected to be initiated by FluoroPharma.

Additional terms of the licensing agreement with MGH require FluoroPharma to meet certain development milestones related to clinical trials and FDA regulatory filings. In the event FluoroPharma fails to hit certain of these milestones, MGH has the right to cancel or make non-exclusive the licenses related to these product candidates. As of 12/31/2012 (the most recent reporting period), FluoroPharma was current with the stipulated milestones. The agreement also calls for FluoroPharma to pay royalties equal to 2% of revenue with a minimum of $50k per year beginning with the first commercial sale.

Current Development Timelines



BFPET

BFPET is a novel blood flow imaging agent being developed for use in conjunction with stress-testing for the detection of ischemic (reversibly damaged) and infarcted (irreversibly damaged) tissue within the myocardium in patients with suspected or proven chronic CAD. BFPET, a Flourine-18 labeled tracer, has been designed to enter the myocardial cells of the heart muscle in direct proportion to blood flow and membrane potential - which are the two most important physiological indicators of adequate blood supply to the heart. BFPET has been designed to effectively differentiate among those cells of the myocardium that are ischemic, infarcted and those that are healthy. Because ischemic and infarcted cells take up significantly less BFPET than normal healthy myocardial cells, the signal emitted by BFPET is inversely proportional to the extent of myocardial injury. Therefore, as a result of BFPET's use, FluoroPharma believes ischemic heart tissue can be more reliably detected using BFPET. BFPET is expected to primarily be used in conjunction with stress-testing for patients with suspected or proven chronic CAD. If approved, BFPET will represent the first molecular imaging blood flow agent commercialized for use in the cardiovascular segment of the PET imaging market.

BFPET has completed phase I trials and is entering phase II trials to assess its efficacy in CAD subjects. Phase II trials will compare BFPET to Rb-82 and/or traditional SPECT agents. Based on current expected timelines, we believe phase II trials will be completed in 2014 or 2015. If all goes to plan, phase III trials could wrap up and an NDA filed by the end of 2016. This potentially puts BFPET on the U.S. market by 2017. We more conservatively model a launch in 2018.

Phase I trials (used to assess safety / tolerability, distribution and dosimetry) consisted of 12 healthy individuals which were injected with one dose of BFPET while at rest (i.e. - not stressed-tested). Results, announced in July 2008, showed a favorable profile on all categories (safety, distribution, dosimetry) and no adverse events were experienced.

BFPET Pre-Phase II Study Results Very Encouraging…

In late July 2012 FlouroPharma announced that quality of the initial images using BFPET in a 20-patient (with coronary artery disease) investigator-led stress perfusion imaging study conducted at a hospital in Beijing China were "spectacular" and "superb". This study is similar in the expected design of the soon-to-commence phase II study where BFPET will be compared to Rb-82 and/or traditional SPECT agents such as sestamibi which (as we detail under "Competition") suffer from certain drawbacks such as high cost or comparably (relative to BFPET) lower image quality.

Alan Fishman, principal investigator of the BFPET phase I trial, notes in the press release relative to the current study that "initial results are impressive. Image quality obtained using PET is superb. BFPET shows clear diagnostic qualities as well as increased resolution, inherent in PET. The initial images look spectacular and we are confident that when all the patients are imaged, the data will further support clinical development of the agent." His confidence was further bolstered when additional data was available in November 2012, noting "We saw a high level of agreement between the angiography, the SPECT and the BFPET images. These additional images demonstrate that BFPET shows clear diagnostic qualities as well as the increased resolution, inherent in PET."

CardioPET

CardioPET is a novel molecular imaging agent (also labeled with Flourine-18) in development for the assessment of myocardial metabolism. FluoroPharma intends to develop CardioPET for use in the following areas: (a) detection of ischemic and infarcted tissue in patients with suspected or proven forms of acute and chronic CAD, including those that cannot undergo stress-testing; and (b) Cardiac Viability Assessment (CVA), for the prediction of functional improvement prior to, or following revascularization in patients with acute CAD, including myocardial infarction.

FluoroPharma believes that CardioPET may be ideal for CVA through its ability to specifically identify jeopardized but viable myocardium - that is, heart tissue that has suffered an acute episode of ischemia, but is still viable. Identifying viable myocardium, also referred to as hibernating or stunned myocardium, from non-viable scar tissue is crucial because it is well documented that revascularization in patients with substantial viable myocardium results in improved left ventricular dysfunction and survival. The company believes that CardioPET, if approved, may have several significant advantages for assessing cardiac viability using PET, and would represent the first imaging agent available in the U.S. for use in patients with acute and chronic CAD that cannot undergo stress-testing. CardioPET is designed to provide the metabolic component for CVA. Accordingly, it may be used with either BFPET or other blood flow agents in performing CVA.

In the acute setting, CardioPET could potentially play a critically important role in emergency rooms, helping to better assess the risk of patients presenting with signs of acute coronary syndrome. Patients coming into emergency departments that show signs of ACS are initially triaged based on a review of their medical history and through some gate-keeper type of tests such as a chest x-ray, EKG and certain biomarker tests such as Troponin. While these tests are generally good for providing information relative to whether someone has recently suffered a cardiac event such as a heart attack, they have certain shortcomings. EKG's have shown to be highly accurate in the confirmation of ACS but suffer from high false positives - which means many low-risk patients may be inaccurately diagnosed as high-risk. Troponin and other biomarker tests, used to detect elevated levels of certain proteins released following a heart attack, are accurate in determining whether a cardiac event occurred but the accuracy of the tests is highly dependent on when they are administered as these biomarkers peak in the body ~8 to 24 hours after the onset of a heart attack. This means triage decisions may be delayed, potentially putting a patient at greater risk.

While these gate-keeper tests are generally valuable for triaging patients to a high-risk group (which should be admitted to the hospital immediately), they provide less guidance for intermediate and low risk groups. This often results in either over- or under-diagnosis and inappropriate follow-on testing and treatment for intermediate and lower risk patients. CardioPET could be ideal adjunctive test for this patient population, which accounts for ~85% of the patients emergency departments see every year with signs of ACS. CardioPET could allow emergency room physicians to better diagnose these patients determine the next course of action - whether it be release and outpatient follow-up or admit to the hospital and treatment.

CardioPET completed phase I trials and in March 2012 FluoroPharma announced the initiation of the phase II trial design. The company signed a letter of intent with SGS Life Sciences to provide clinical research services for phase II trials of CardioPET - this agreement was consummated in September 2012 when the companies signed a Clinical Research Agreement. The Belgian-based trial is open label and designed to assess safety and performance of compared to stress echocardiography, myocardial perfusion imaging (MPI) and angiography. The trial will be conducted at two sites in Belgium. Enrollment is expected to consist of between 30 and 100 patients with known stable chronic coronary artery disease that can not undergo stress testing.

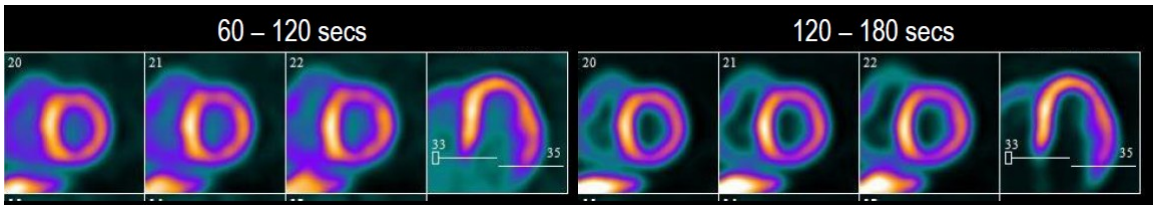
CardioPET data to-date has been consistently very positive and our expectations that follow-on results from the phase II studies, which we think will be upcoming, will be similarly positive. Phase I trials (used to assess safety / tolerability) consisted of 6 patients with diagnosed CAD and 15 normal healthy volunteers (i.e. - control group). Phase I testing completed in April 2007 and demonstrated CardioPET was safe with no patients experiencing any adverse events.

In late February 2013 FPMI announced that the initial images from the phase II trial "show high resolution in the heart and provides extremely clear image quality". Then in June the company announced that an internal review of additional data from this study supported earlier findings of excellent image quality. While FPMI did not provide specifics on the images in the June press release, Dr. Manual Cerqueira, Chairman of the Department of Nuclear Medicine at the Cleveland Clinic was quoted and noted, "The images thus far obtained from CardioPET indicate excellent image quality. The immediate acquisition of images will be very efficient for patient work flow." The interim data, which was finally revealed (as discussed below) in early February 2014 at the Society of Nuclear Medicine and Molecular Imaging Meeting in Palm Springs, did not disappoint and provided the most substantive evidence to-date of the potential performance benefits of CardioPET over current standard imaging agents.

Promising Phase II Data Reinforces Our Confidence in CardioPET….
The data presented in February relate to assessment of the safety of CardioPET, image quality and in determination of the optimal timing for PET imaging after injection. Future data from the study will compare results to that of SPECT myocardial perfusion imaging agents.

Fifteen patients with known or suspected coronary artery disease were included in the analysis. Images were taken in three to five minute durations at intervals of one to ten minutes and at 15, 30, 45 and 55 minutes after injection. Image quality was graded as either optimal, sub-optimal or non-interpretable. Changes in blood pool activity, liver activity and delineation defects over time were recorded.

Relative to safety, there were no adverse events and no other safety issues related to CardioPET (one patient had a panic attack from being in the imaging system). Relative to quality of the images and performance of CardioPET, images at all time points from three minutes following injection were considered excellent. Blood pool activity began to decline in the initial one to three minute timeframe and blood pool clearance was totally completed in all patients at five minutes (image below). Rapid blood pool clearance is beneficial as it allows for imaging shortly following injection and reduces patient exposure to imaging radiation.



CardioPET enters the myocardium similar to the way of fatty acids and remains there long enough to allow for PET imaging. The images also showed that fatty acid uptake decreased over time. In ischemic heart conditions, uptake of fatty acids is reduced, which would be expected in these patients.

The interim data, image quality and safety was considered very promising. The ability to attain high quality images very shortly after injection is of particularly benefit and significant. We expect there will be additional data and images presented in the near-term and expect similarly positive results. This interim data reinforces our belief that CardioPET has potential to unseat the current standard imaging agents for coronary artery disease imaging, particularly for those patients unable to undergo stress testing.

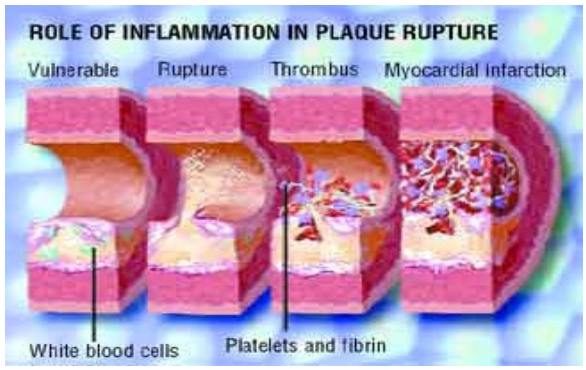
We view this news as an obvious and significant positive for FPMI and their CardioPET candidate and our outlook remains highly positive on FPMI. If all goes to plan phase II will wrap up in 2014 and phase III completed and an NDA filing potentially happening by the end of 2015. U.S. launch could potentially happen by 2016. We more conservatively model a launch in 2017.

VasoPET

FluoroPharma is developing VasoPET as a novel molecular imaging agent for the detection of vulnerable coronary artery plaque in patients with CAD. VasoPET, if approved, would represent the first PET cardiac product to reliably image inflamed plaque and therefore may differentiate between vulnerable and stable coronary artery plaque.

The rupture of atherosclerotic plaques and the subsequent formation of thrombi are currently recognized as the primary mechanisms of myocardial and cerebral infarctions. Therefore, the detection of vulnerable plaque in atherosclerotic lesions is a desirable goal—and to date remains both a significant unmet clinical objective and a large unaddressed market opportunity.

Role of Inflammation in Plaque Rupture



SOURCE: www.diagnosticimaging.com

Coronary artery plaques grow over time and progressively narrow the lumen (i.e. - opening) of the coronary artery until blood flow to the heart diminishes to a critical level. The decrease in blood flow causes symptoms of chest pain (angina), at first during exercise and then progressively during rest. Rupture of the plaque and/or clot formation overlying the plaque may then result in myocardial ischemia and/or myocardial infarction. Coronary artery plaque that is vulnerable is differentiated from its stable form by a large lipid-rich atheromatous core, a thin fibrous cap, and infiltration by inflammatory cells such as macrophages. The risk factor for rupture (and subsequent heart attack) is currently thought to be independent of plaque size and arterial narrowing, but rather is thought to correlate more with the presence of inflammation.

VasoPET has completed preclinical testing and preparation for an investigational new drug (IND) application is currently ongoing. Based on current expected timelines, an IND could be filed and phase I trials started towards the back half of 2014. However, FPMI recently indicated that due to its limited patent life (U.S. patent expires in 2016) that they may decide to not pursue further development of VasoPET. As we had yet to model any contribution from VasoPET, a delay or an altogether scrapping of development of the candidate has no effect on our revenue projections

Reimbursement for FPMI's Products…

CMS bundles reimbursement for diagnostic radiopharmaceuticals in the technical component. For new diagnostic radiopharmaceuticals, reimbursement can be provided through a pass-through code. Assuming FluoroPharma's agents receive FDA approval, they will apply to CMS for an HCPCS (Healthcare Common Procedure Coding System) pass-through code. This is a temporary code whereby imaging facilities can receive reimbursement when using these radiopharmaceuticals prior to a permanent CPT code being assigned. Reimbursement under these pass-through codes is paid at either ~ 95% of the wholesale price or 106% of the average sales price. When reimbursed through pass-through, CMS applies an off-set to the technical component (to ensure against duplicate payment for the radiopharmaceuticals).

FluoroPharma will then apply for permanent CPT codes which would allow reimbursement to be packaged with a specific procedure in which the tracers are used. Assignment of CPT codes could take anywhere from 3 months to 18 months after the application is filed.

MARKETS

BFPET Market: *Myocardial Perfusion Imaging*

BFPET will be used to measure cardiovascular blood flow in MPI exams. Approximately 10 million perfusion imaging exams are performed in the U.S. every year. SPECT currently dominates this market although, as noted, SPECT suffers in image quality compared to PET. PET MPI exams use the tracer Rb-82 which, as noted, is relatively expensive which has limited its use. FluoroPharma expects to capitalize on the deficiencies of SPECT and Rb-82 by positioning their Flourine-18 labeled BFPET tracer as a high accuracy, relatively safe agent for MPI.

BFPET will be used with PET in combination with stress testing for the identification of ischemic and infarcted tissue in patients with chronic CAD (approximately 85% of CAD is considered chronic as opposed to acute) as well as in combination with FDG (or CardioPET) in patients with acute CAD that are undergoing CVA.

The potential market for BFPET is huge - essentially encompassing the entire MPI procedural population. However, as the vast majority of MPI procedures are done using a modality other than PET, the proportion of this market that BFPET would realistically be able to initially attain would likely be relatively low. But, due to the rapidly growing acceptance of PET in cardiac diagnostics along with the advantages of BFPET compared to Rb-82, deeper penetration within MPI could come fairly swiftly. FluoroPharma estimates that PET will account for approximately 5% of the U.S. molecular imaging market by 2015 and 25% share within five years after BFPET makes its commercial launch (both of which are very conservative relative to the estimates cited in the aforementioned market study). They also believe BFPET could eventually capture approximately 65% share of the evaluable cardiovascular PET market.

Based on these assumptions, FluoroPharma estimates that BFPET could capture about 1% - 3% of the total market for MPI radiopharmaceuticals in the first full year after launch (i.e. - possibly ~2017/2018) and will account for about 20% - 30% of the market five years following launch (i.e. - possibly ~ 2022/2023) - which, depending on the selling price that the company is able to achieve, could mean revenue to FluoroPharma from sales of BFPET as high as $50 million in the first full year after launch and ~ $700 million five years after launch.

CardioPET: *Cardiac Viability*
CardioPET's chief clinical uses are expected to be to identify patients with jeopardized but viable myocardium that will benefit from PCI and in the evaluation of CAD in patients that can not exercise. PET imaging using CardioPET will be positioned as an alternative to exercise stress-testing. CardioPET's target markets will be the approximately 4 million patients with chronic CAD that can not undergo exercise stress testing, the 1.6 million people that could benefit from cardiac viable assessment, and a portion of the 12 million MPI procedures. As there are no directly competing tracer products in the non-stress testing indication, FluoroPharma expects to be able to capture a significant portion of this segment shortly after launch. Within five years of launch FPMI believes that they can attain as much as 80% share for the myocardium viability indication, 30% of the CAD diagnosis at rest indication, and 7% of the MPI indication. Based on these assumptions, the company believes that within the third year of launch, CardioPET could be used in approximately 700k procedures, growing to 1 million+ procedures in year five post-launch. This could equal a potential revenue opportunity to FluoroPharma of approximately $400 million in the third year (i.e. - ~2019/2020) and $600+ million in the fifth year (i.e. - ~2021/2022) after launch.

COMPETITION

While there are no current commercially available direct competitors to FluoroPharma's agents from a specific indication-to-indication standpoint, PET tracers such as FDG and Rb-82 and other imaging modalities represent the current broad competitive landscape.

Other companies are working on development of more specific competing agents, however:

- Proportional Technologies, Inc. (PTI) is developing, **MyoPET** (or Cu-PTSM), a copper (II) bis(thiosemicarbazone) compound, for the measurement blood flow and the detection of CAD with PET either at rest or stressed. Phase III studies showed MyoPET was as good or better than SPECT (with technetium-99 or thallium-201) in the detection of CAD. PTI submitted an NDA for MyoPET and the FDA returned with an approvable letter in 2002 asking for data from a longer safety monitoring period and improvement on the statistical significance of the efficacy endpoints. It is unclear what the current development status is of MyoPET.

- In July 2011 Lantheus Medical Imaging initiated phase III testing of its novel fluorine 18-labeled PET agent, **Flurpiridaz** for the assessment of myocardial perfusion. Flurpiridaz MPI is being compared to SPECT MPI in the detection of significant CAD. Secondary endpoints include the localization of significant CAD and the identification of multi-vessel disease. Phase II data, presented in May 2011, showed Flurpiridaz was superior to SPECT in image quality and the detection of CAD. Preliminary results from Phase III, announced in October 2013, showed that while Flurpiridaz had better sensitivity (i.e. – identifying disease), it missed the other secondary endpoint, that being superior specificity (i.e. – ruling out disease). Nonetheless, Lantheus indicated

high image quality and noted that they will forge ahead with phase III studies. Assuming no significant setbacks, Flurpiridaz would likely make it to market well ahead of any of FluoroPharma's products.

- B-methyl-p-[123I]-iodophenyl-pentadecanoic acid (or **BMIPP**), a novel cardiac SPECT tracer, is in late stage development in the U.S. It is already commercially available in Japan where it is used in approximately 20% of all nuclear cardiology studies. If approved in the U.S., it would represent direct competition to CardioPET. Similar to CardioPET, BMIPP is a methyl fatty acid that is retained by myocardial cells. Molecular Insight Pharmaceuticals is developing BMIPP under the name Zemiva. The initial target market for Zemiva is for the rapid diagnosis of myocardial ischemia or heart attack in the emergency department setting in chest pain patients, many of whom have an uncertain diagnosis after initial evaluation. Phase II trials showed Zemiva was more sensitive than the comparator (electrocardiograms and troponin testing) in the detection of acute coronary syndrome in patients with no history of myocardial ischemia. There were no reported severe adverse events in the BMIPP group. Safety profile was considered excellent. In March 2009 Molecular Insight noted that they expected to begin phase III trials in 2010, although it does not appear that phase III trials have actually commenced.

  FluoroPharma believes CardioPET has distinct advantages over BMIPP, including; 1) BMIPP is a SPECT agent and therefore suffers from the lower accuracy of SPECT compared to PET, 2) BMIPP must be manufactured at a single site (in Vancouver, B.C.) and delivered the next day for use, due to the short (13 hour) half-life of [123I]. In contrast, CardioPET can be manufactured locally by adding [18 F] to a precursor to be manufactured by FluoroPharma. The precursor is chemically stable and should have a long shelf-life. Production and distribution channels for [18 F] are becoming increasingly well-established. These differences should make CardioPET far more convenient and cheaper than BMIPP. 3) CardioPET is quantifiable, whereas BMIPP is not.

FINANCIAL CONDITION

Cash
Cash used in operating activities was $1.3M in Q4 up from an average of $667k in the first three quarters of the year. Ex-changes in working capital, cash used in operating activities in Q4 was $1.1M, up from an average of $800k in the first three quarters of the year. Cash burn averaged about $830k/quarter in 2013, roughly flat from 2012.

FPMI exited 2013 with $1.1M in cash and equivalents plus $635k in tradable securities (NAVB common stock acquired via the Q3 preferred stock sale). Subsequent to quarter end raised an additional $235k (gross) from the sale of common shares.

STRATEGY / OUTLOOK

According to current development timelines, product commercialization and revenue generation is at least two to three years away. From now until then FluoroPharma will need to clear several requisite milestones - the most significant of which we detail below.

CLINICAL TRIALS
In 2012 FPMI brought on SGS Life Sciences to act as the CRO for phase II trials of CardioPET. The trial is being conducted at two sites in Belgium. The trial is open label and designed to assess safety and performance of CardioPET compared to stress echocardiography, myocardial perfusion imaging (MPI) and angiography. Enrollment is expected to consist of between 30 and 100 patients with known stable chronic coronary artery disease that can not undergo stress testing.

In early January 2013 FPMI announced that phase II trials of BFPET will be conducted at Massachusetts General Hospital. Similar to the investigator-led study, the phase II study will compare BFPET to Rb-82 and/or traditional SPECT agents such as sestamibi which suffer from certain drawbacks such as high cost or comparably (relative to BFPET) lower image quality. The specific trial design will be announced prior to the commencement - until then we estimate BFPET enrollment will also be approximately 50 patients.

We estimate aggregate cost of phase II trials for both CardioPET and BFPET at about $1.5 million. FluoroPharma has indicated that they expect the duration of the BFPET phase II trials will be approximately 12 months, while the phase II CardioPET trials will take approximately 15 months. Important to note is that these diagnostic drug trials can be accomplished in significantly less time than typical therapeutic drug trials as, for one, there is no patient follow-up with imaging studies (patient follow-up can be several months or even years with therapeutic drug trials).

Meanwhile, VasoPET which is currently in an earlier stage likely will not commence clinical (i.e. - phase II) trials for two years or more, if ever. Current development timelines imply the earliest VasoPET would likely make it to market will be 2017. However, FPMI recently indicated that due to the impending expiration (2016) of the U.S. patent of VasoPET, that they may discontinue development of the candidate. As such and for simplicity purposes, the remainder of this Strategy / Outlook section relates mostly to BFPET and CardioPET.

Based on current timelines, phase III trials for CardioPET and BFPET could start sometime in 2014 and 2015, respectively and possibly wrap up within about 12 months. These will be significantly larger than phase II - possibly enrolling anywhere between 300 and 700 patients per trial. These will also be significantly more expensive - potentially costing as much as $10 million each (i.e. - $20 million total). FluoroPharma may look to enter into a partnership to help fund phase III trials - the consummation of which could be facilitated by strong phase II data.

REGULATORY APPROVAL
Assuming phase III data is positive, FluoroPharma will submit for FDA approval via an NDA. FDA response could be anywhere between 6 months (assuming expedited status) to one year or more. If all goes smoothly without any significant delays (in either the development or regulatory processes), it is possibly that CardioPET and BFPET could be approved for sale in the U.S. sometime in 2016 and 2017, respectively. We model a more conservative timeline which assumes CardioPET launches in 2017 and BFPET in 2018.

REIMBURSEMENT
Reimbursement under Medicare will be essential for there to be any demand for FluoroPharma's products. Following FDA approval the company can apply to CMS for an HCPCS pass-through code. Assuming pass-through codes are assigned, they must be used for at least two years but not more than three years. FluoroPharma will also apply for permanent CPT codes which would allow reimbursement to be packaged with a specific procedure in which the tracers are used.

The rate of reimbursement could not only effect margins to the imaging facility (which could also potentially effect demand for FPMI's products), it could also influence FPMI's pricing and profitability. While it's much too early to speculate with any degree of confidence whether an eventual rate of reimbursement might offer a reasonable margin to FPMI (an estimate of which also requires a number of other inputs - most notably demand and cost to manufacture, sell and distribute), based on generalized gross margins within the radiopharmaceutical development industry, which can run as high as 99%, we think it's reasonable to assume that FPMI could generate an attractive return.

MANUFACTURING / SALES / DISTRIBUTION
FluoroPharma currently has no manufacturing capabilities. Barring a strategic partnership agreement that brings with it these assets and expertise, the company will need to either secure these themselves or (more likely) license with an existing radiopharmaceutical manufacturer. Likewise, distribution could also be handled through a third party and outsourced to the likes of Cardinal Health or Covidien (among other distributors). As a large portion of the end-user market is fairly concentrated, the direct sales function could potentially be done in-house by a small sales team.

VALUATION / RECOMMENDATION

Assigning valuation of FluoroPharma is somewhat tricky given that the first commercial product launch is still at least several years away. There are also no publicly available acquisition transactions in the radiopharmaceutical space involving a target company similar to FluoroPharma that could be used to value the company.

As a result, we believe an appropriate valuation methodology is to use price/sales ratio based on an estimate of revenue two to three years after when the first product may launch. Based on management's assumptions relative to demand for their products and growth of the respective markets, estimated revenue in 2019 could be as much as

$1.7 billion. We have significantly haircut these estimates as we think these may be more of a best-case scenario. We use a 2.5x price/sales multiple to our estimated (i.e. - ballparked) 2020 revenue of $130 million and discount this back to the present at a fairly lofty 25%/year. We feel this discount rate is appropriate given that product development is still at an early enough stage where there is not insignificant risk of failure to hit expected milestones, including eventual FDA approval and commercialization. These inputs result in a current valuation of approximately $58 million, or about $2.15 / share.

We have also built a DCF model through 2024 which also supports a valuation of approximately $2.15. Key inputs to our DCF model are initial revenue commencing in 2017 and growing to around $240 million (this is downward revised due to the delays with BFPET) in 2022 and a ~14% cash flow discount rate (we have reduced the discount rate to reflect reduced risk as a result of progression with CardioPET phase II studies and related positive data to-date). We feel our current discount rate still fairly represents the inherent risks of FPMI's development-stage status. Our DCF model calculates a valuation of $2.35.

Depending on the progression, success and timeliness of product development and related likelihood of ultimate FDA approval / commercialization, it may be appropriate to again revisit the discount rates used in both valuation methodologies. Similarly, depending on how certain other factors evolve over the next few years such as the reimbursement environment for radiopharmaceuticals, growth of PET for cardiac applications, and the competitive landscape for novel PET cardiac tracers, it may prompt modifications (up or down) to our forecasted revenue and cash flow estimates. As it is now we value FPMI at $2.15/share. Based on the current share price of $0.66, we feel the stock remains undervalued and are maintaining our Outperform rating.

Potential risks to our recommendation include:

- Company will require additional capital or partnership agreements to fund later-stage clinical trials. Additional equity financing may dilute current shareholders and depress the share price. Inability to raise capital or partner in order to fund phase III testing would significantly jeopardize the company's future.
- FDA approval, assuming it happens, is likely to be at least two to three years away. Significant delays in product development or regulatory approval would likely negatively impact our financial estimates and our related valuation of the company.
- Adverse changes to radiopharmaceutical reimbursement could continue, potentially reducing eventual demand for FPMI's tracers. There are also no guarantees that FPMI's products will be covered through the assignment of CPT codes - which could limit their demand (especially over the linger-term).
- These are novel tracers that will compete against much more established radiopharmaceuticals which could hamper uptake.
- FPMI has no manufacturing or sales/marketing infrastructure or experience.

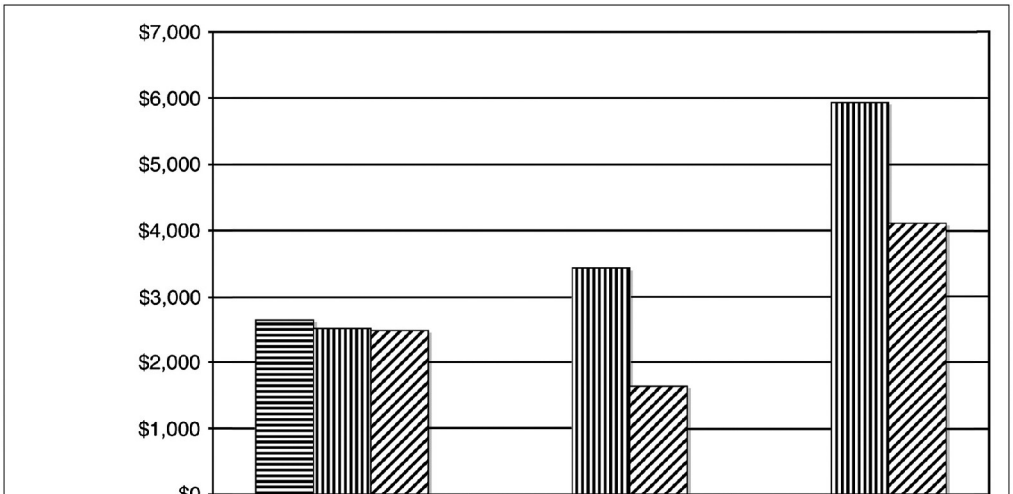
APPENDIX

Cost/Benefit of PET vs. SPECT

While the enhanced accuracy of PET over SPECT is widely accepted, as PET scans are more expensive than are SPECT, there is some debate whether PET's greater accuracy translates into overall cost savings due to a reduction in unnecessary procedures. Proponents of PET cite a large study by researchers at SUNY Buffalo as evidence that it does. The study, titled *Impact of Myocardial Perfusion Imaging with PET and RB-82 on Downstream Invasive Procedure Utilization, Costs, and Outcomes in Coronary Disease Management,* compared PET with SPECT in myocardial perfusion imaging of patients likely to have coronary disease with the goal of determining whether PET would reduce downstream utilization of (invasive) diagnostic coronary arteriography (~$5k per procedure). In building their hypothesis the authors noted, "Compelling evidence has demonstrated that invasive procedures such as coronary arteriography, coronary artery bypass grafting (CABG), and percutaneous transcoronary intervention (PTCI) are overutilized in the United States, contributing to unnecessary health care expense without improved patient outcomes." In the end, the study found that use of PET over SPECT reduced the number of coronary arteriography and CABG procedures by over 50% and reduced overall costs by 30% (with no significant difference in myocardial infarction after one year) - which provides support for the use of PET over SPECT from both a patient care as well as a long-term overall cost standpoint.

Relative to overall diagnostic cost, the study found specifically that although SPECT procedures are less costly, this cost advantage over PET was lost (see table below - diagnostic costs are ~ equal) because a greater percentage of SPECT patients required a coronary arteriography procedure (i.e. - definitive diagnosis). The study found that approximately 25% of all patients (in both the PET and SPECT cohorts) that underwent coronary arteriography also received CABG (~ $40k per procedure). Therefore the total cost savings ($4,110 vs. $5,937 - in table) with PET was gained through lower therapeutic (revascularization) costs with PET patients due to lower CABG utilization.

PET Cost Benefit vs. SPECT



	Diagnostic costs	Therapeutic costs	Total costs
END study (*n* = 5826)	$2,632		
SPECT (*n* = 102)	$2,506	$3,431	$5,937
PET (*n* = 2159)	$2,475	$1,635	$4,110

SOURCE: Merhige ME, Breen WJ, Shelton V, et al. Impact of myocardial perfusion imaging with PET and (82)Rb on downstream invasive procedure utilization, costs, and outcomes in coronary disease management. J Nucl Med.2007;48:1069-1076. The Journal of Nuclear Medicine.

MANAGEMENT / ADVISORS

Thijs Spoor – *Chairman, CEO & President*
Mr. Spoor previously held the title of CFO for Sunstone BioSciences. Mr. Spoor holds a Nuclear Pharmacy degree from the University of Toronto as well as an M.B.A. from Columbia University with concentrations in finance and accounting. Mr. Spoor has been a guest lecturer at Columbia Business School, Kings College in London and the University of Newcastle in Australia and has presented at medical grand rounds and psychiatric grand rounds at various hospitals on the role of brain imaging. Prior to joining Sunstone BioSciences, he worked as a consultant at Oliver Wyman focusing on helping pharmaceutical and medical device companies evaluate their global revenue potential given the complex interplay of regulatory approvals, the reimbursement environment, as well as the impact of physician preference within constantly evolving standards of care. He further specialized on the implications of healthcare reform on new product approval and health insurance reform. Mr. Spoor has also been an equity research analyst at J.P. Morgan and Credit Suisse covering the Biotechnology and Medical Device industries. Mr. Spoor worked in the pharmaceutical industry spending 10 years with Amersham / GE Healthcare where he worked in 7 countries in a variety of roles including setting up GMP facilities meeting ISO 9001 standards, accountability for the entire nuclear cardiology portfolio and most recently as the Director of New Product Opportunities leading the PET strategic plan.

Boyan Goumnerov, MD – *COO & Vice President Clinical Trials*
Prior to his appointment with FluoroPharma Dr. Goumnerov has held executive positions in the healthcare and biomedical research fields most recent of which are President of VasoStent, Inc. and managing director of CardioVas Inc.- start-up medical device companies targeting the field of intravascular cardiac imaging and therapy. His academic background includes research within the departments of Surgery and Molecular Biology at the Massachusetts General Hospital (MGH) and The Shriners Burn Hospital for Children, Boston, where he held academic appointments with Harvard Medical School. Dr. Goumnerov also did extensive work within the Department of Pathology/Neuropathology at Children's Hospital Boston, in developing image analysis protocols for evaluation of neuromuscular diseases before moving to MGH. He is co-author of numerous scientific publications. Dr. Goumnerov obtained his M.D. from the Medical University of Sofia, Bulgaria, and worked as a clinician prior to relocating to the US.

Tamara Rhein - *CFO*
Ms. Rhein joined FluoroPharma in 2011 as Controller. Prior to FluoroPharma, she was Controller of Manhattan Pharmaceuticals, where in addition to maintaining the critical financial functions for the company, she was also responsible for a wide range of activities including financial statement preparation, footnote disclosures for SEC filings, stock option accounting and quarterly and year-end audits. Before Manhattan Pharmaceuticals, Ms. Rhein was with Vyteris, where her primary role was to manage the SEC accounting and reporting department. In addition to her financial responsibilities, Ms. Rhein worked with the CEO on the launch of a new product. In this capacity, she managed critical aspects of coordination, timing and tracking of the initiative.
Before joining Vyteris, Ms. Rhein was Vice President of New Business at Credit Suisse First Boston, where she provided comprehensive research and analysis to guide Senior Management on certain projects and complex business transactions.

Prior to its merger with Credit Suisse First Boston, Ms. Rhein was a Vice President of External Reporting at Donaldson, Lufkin & Jenrette, where she prepared and reviewed SEC filings for both Donaldson, Lufkin & Jenrette and Donaldson, Lufkin & Jenrette direct. She was extensively involved in the Initial Public Offering of the Donaldson, Lufkin & Jenrette direct tracking stock issued in May 1999. Ms. Rhein began her career as a Senior Auditor for Deloitte & Touche, where she planned and administered audit engagements for several large banks and insurance companies. Ms. Rhein received a Bachelor of Science in Accounting from California State University, and is a Certified Public Accountant.

Walter Witoshkin – *Director*
Walter Witoshkin, is an accomplished executive with 40-years experience in the pharmaceutical, healthcare and biomedical industries. Mr. Witoshkin specialized in alternative sourcing for manufacturing and the acquisition of technologies and products. Mr. Witoshkin previously held executive positions with QuantRx Biomedical Corporation, a medical technology company with leading edge diagnostic and therapeutic technologies. Mr. Witoshkin has previously held executive positions in the healthcare and pharmaceutical industries including senior financial positions at Wyeth Labs (American Cyanimade), VP Business Development and CFO positions at SmithKline Beecham (now Glaxo SmithKline) and Menley & James Laboratories, Inc. He is a founding partner of the Trident Group, a global consultancy to the pharmaceutical industry. He is Chairman of the Board at QuiqMeds Inc.

Peter Conti, MD, PhD – *Director, Scientific Advisory Board*
Dr. Conti is Professor of Radiology, Biomedical Engineering and Pharmacy at the University of Southern California. He has been the Director of the USC PET Imaging Science Center since its inception in 1991. He served as the President of the Society of Nuclear Medicine and is a major contributor to the development of clinical PET and molecular imaging. One of Dr. Conti's major research interests is in the development of molecular imaging agents for the diagnosis and monitoring of cancer metabolism and cell proliferation. Dr. Conti is Board certified in both Diagnostic Radiology and Nuclear Medicine. He received both his MD and PhD degrees from Cornell University.

Lawrence Atinsky - *Director*
During the past seven years Mr. Atinsky has been a partner at Ascent Biomedical Ventures (ABV), a venture capital firm investing in seed and early-stage biomedical technology companies developing medical devices, biopharmaceuticals, healthcare services, and information technology. Prior to joining ABV, Mr. Atinsky was a Mergers & Acquisition attorney at Skadden, Arps, Slate, Meagher & Flom in New York, where he was involved in structuring and negotiating numerous private and public transactions. Mr. Atinsky has also been the General Counsel of several private companies in the healthcare industry and has been a founder and investor in early-stage medical technology companies. Mr. Atinsky earned a JD from New York University School of Law and B.A. degrees in Political Science and Philosophy from the University of Wisconsin-Madison.

Joseph A. Pierro - *Director*
Since July 2012 Dr. Pierro has been the Chief Medical Officer at Biomedical Systems, a provider of diagnostic services for clinical trials, where he is responsible for leadings its Scientific Affairs groups which provide medical and regulatory guidance with respect to clinical studies. From April of 2009 until May of 2012, Dr. Pierro served as Vice President, Head of Medical Science at Covidien, a healthcare products company, and from July of 2005 until April of 2009 Dr. Pierro served as the Vice President, Clinical Affairs at Covidien where Dr. Pierro was responsible for providing strategic medical direction and operation regulatory and clinical support for new product development. From April 2001 until July 2005, Dr. Pierro served in various medical and clinical roles at General Electric Health Care. Dr. Pierro earned his M.D. at the State University of New York at Buffalo School of Medicine and his undergraduate degree from Canisius College.

PROJECTED INCOME STATMENT

FluoroPharma Medical, Inc.

	2013 A	Q1 E	Q2 E	Q3 E	Q4 E	2014 E	2015 E	2016 E	2017 E
CardioPET	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$3.6**
YOY Growth	-	-	-	-	-	-	-	-	
BFPET	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
YOY Growth	-	-	-	-	-	-	-	-	
VasoPET	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
YOY Growth	-	-	-	-	-	-	-	-	
Other Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
YOY Growth	-	-	-	-	-	-	-	-	
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$3.6**
YOY Growth	-	-	-	-	-	-	-	-	
Cost of Goods Sold	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1.0
Gross Margin	-	-	-	-	-	-	-	-	*73.0%*
Sales, General & Admin	$3.0	$0.9	$0.9	$0.8	$0.9	$3.5	$3.7	$4.2	$5.2
% SG&A	-	-	-	-	-	-	-	-	-
Research & Development	$1.3	$0.4	$0.6	$1.0	$1.2	$3.2	$6.5	$7.0	$7.0
% R&D	-	-	-	-	-	-	-	-	-
Depreciation & Amortization	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($4.4)	($1.3)	($1.5)	($1.8)	($2.1)	($6.7)	($10.2)	($11.2)	($9.6)
Operating Margin	-	-	-	-	-	-	-	-	-
Interest & Other Income	($1.2)	($0.3)	($0.0)	($0.1)	($0.1)	($0.5)	($0.0)	($0.0)	($0.0)
Pre-Tax Income	$5.6	(1.6)	(1.5)	(1.9)	(2.2)	$7.2	$10.2	$11.2	$9.6
Taxes + Other	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Preferred Stock	$1.7	$0.2	$0.2	$0.3	$0.3	$1.0	$1.3	$1.4	$1.0
Net Income	($7.3)	($1.8)	($1.7)	($2.2)	($2.5)	($8.2)	($11.5)	($12.6)	($10.6)
Net Margin	-	-	-	-	-	-	-	-	-
Reported EPS	**($0.30)**	**($0.07)**	**($0.06)**	**($0.08)**	**($0.09)**	**($0.30)**	**($0.25)**	**($0.21)**	**($0.16)**
YOY Growth	-	-	-	-	-	-	-	-	-
Weighted Ave. Shares	24.4	25.9	27.5	28.0	28.0	27.4	46.0	60.0	65.0

Brian Marckx, CFA

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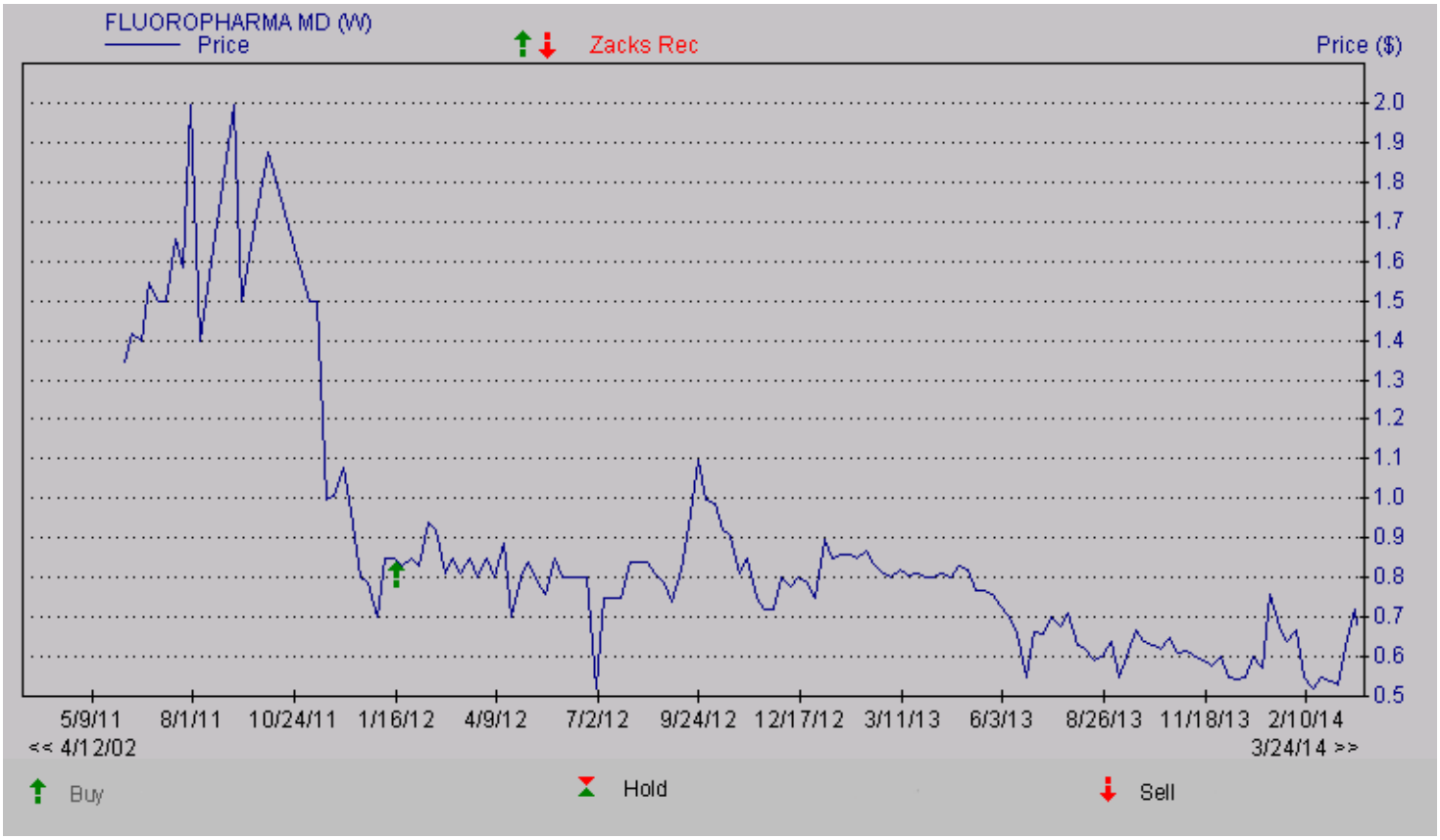

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