Zacks Small-Cap Research

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FluoroPharma Md (FPMI-OTCBB)

FPMI: CardioPET Phase II Trials Initiated

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	01/16/2012
Current Price (03/21/12)	$0.80
Target Price	**$2.00**

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 five years. 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 a highly qualified team with significant and directly applicable experience in the successful development of radiopharmaceuticals. FPMI is a development-stage company, an investment in which carries inherent meaningful risk.

We are maintaining our Outperform rating and $2.00/share price target.

SUMMARY DATA

52-Week High	**$1.05**
52-Week Low	**$0.70**
One-Year Return (%)	**N/A**
Beta	**0.00**
Average Daily Volume (sh)	**25,647**
Shares Outstanding (mil)	**21**
Market Capitalization ($mil)	**$17**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
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 2012 Estimate	**N/A**
P/E using 2013 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**N/A,**
Type of Stock	**N/A**
Industry	**Med Products**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2012	0.0 E	0.0 E	0.0 E	0.0 E	0.0 E
2013					0.0 E
2014					0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.02 A	-$0.18 A	-$0.02 A	-$0.04 A	-$0.25 A
2012	-$0.05 E	-$0.04 E	-$0.04 E	-$0.04 E	-$0.18 E
2013					-$0.23 E
2014					-$0.24 E

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

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WHAT'S NEW…

2011 10-K Filed

FluoroPharma filed their 10-K for the fiscal year ending December 31, 2011 on March 16th. Operating expenses were approximately $870k and $3.4 million for the fourth quarter and full year respectively, compared to $380k and $890k for the year earlier periods.

Net loss to common (includes the $977k accrued preferred stock dividends expense) and EPS were $4.4 million and ($0.25) in 2011 compared to $954k and ($0.08) for 2012.

Cash used in operations was $2.3 million in 2011 including $711k in Q4. Cash balance at 12/31/2011 stood at $3.3 million, essentially flat from the end of Q3 and benefitting from approximately $940k in net proceeds raised from the sale of equity during the most recent quarter.

As there were no surprises in the 10-K and product development has been tracking our expectations, despite making some relatively immaterial tweaks to our model following the year-end report, our outlook as well as price target and recommendation all remain intact.

CardioPET Phase II Trials Initiated

CardioPET, being developed for the assessment of myocardial metabolism, is now entering phase II trials in the assessment of myocardial perfusion and fatty acid uptake in coronary artery disease patients. As we noted in our initiation report on FluoroPharma earlier this year, initiation of phase II trials for CardioPET would be a significant milestone as the agent is expected to be one of FPMI's first products to reach commercialization. If eventually approved by the FDA, CardioPET is expected to offer a better alternative to stress-testing, a very large and rapidly growing opportunity.

In early March FluoroPharma announced they signed a letter of intent with SGS Life Sciences to provide clinical research services for Phase II trials of CardioPET. The Belgian-based trial will be open label and designed to assess safety and performance of CardioPET compared to stress echocardiography, myocardial perfusion imaging (MPI) and angiography. The trial will be conducted at two sites in Belgium with results anticipated in 2H 2012 - which is inline with our previously expected timeline. Per the recent 10-K, enrollment is expected to consist of between 30 and 100 patients with known stable chronic coronary artery disease that can not undergo stress testing.

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 about to enter phase II clinical trials (CardioPET, began Ph II in Q1 2012). 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 five 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 five 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.

FluoroPharma was founded in 2003 by Dr. David Elmaleh and is led by management and directors with extensive experience in the radiopharmaceutical and medical technology industries. Dr. Elmaleh, FluoroPharma's acting Chief Scientific Officer, has created radiopharmaceuticals that are in use today and is credited with the invention over 40 patents including those related to novel molecular imaging compounds in the diagnosis of cardiovascular disease.

The company went public through a May 16, 2011 reverse merger. The financial information included in SEC filings prior to the merger relate to Commercial E-Waste Management, Inc, an electronics waste management solution provider, specializing in the collection, retirement, storage and remarketing of excess, damaged or obsolete electronic assets, such as computer, telecommunications and other electronic office equipment. Concurrent with and shortly following the merger, FluoroPharma raised approximately $4.6 million (net proceeds) in capital. FluoroPharma raised another $1.0 million (gross) from the additional sale of common stock in December 2011. The current cash balance may possibly be enough to fully fund completion of phase II clinical trials for the two products furthest along in development. Phase III trials would require substantially more capital and will necessitate either additional financing or support via partnership / licensing agreements.

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

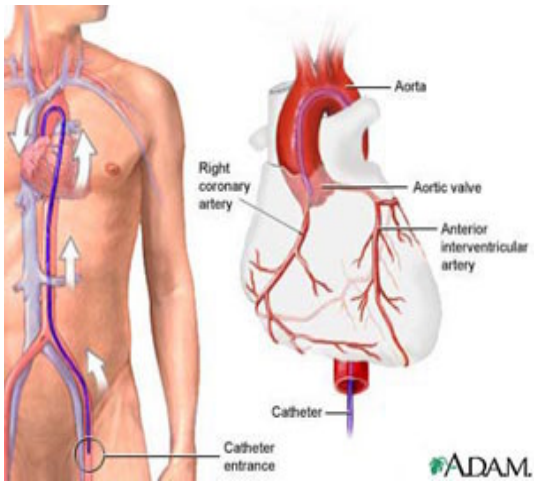


SOURCE: wikipedia.com

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 radiopharmaceuticals compared to SPECT, which contributes to the greater sensitivity of PET.

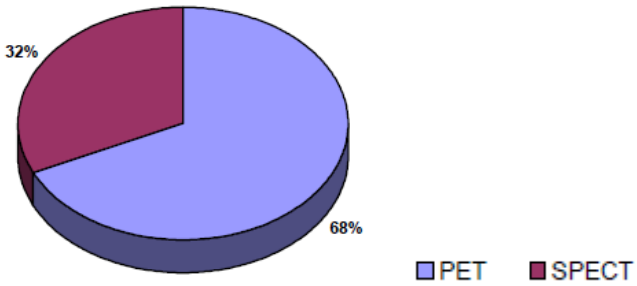


SOURCE:www.medicalcityhospital.com

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.

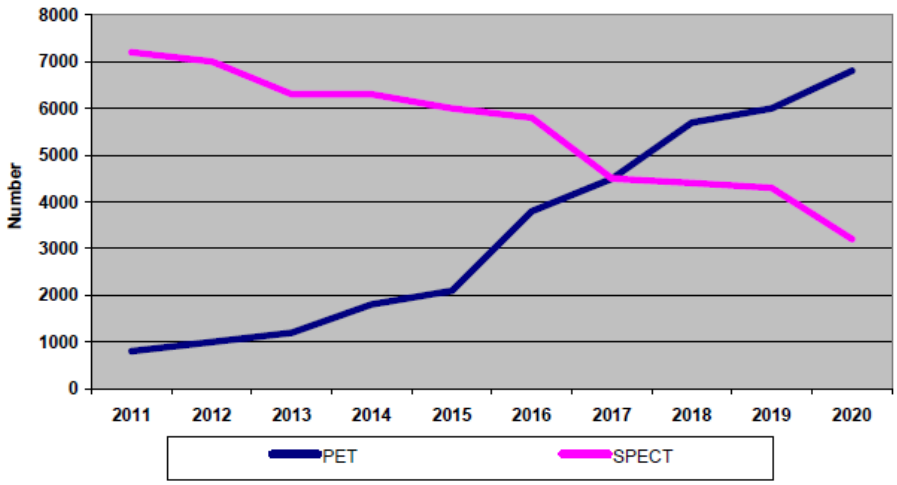
The tides are turning however, with rapid growth in the number of dedicated PET centers and technological advancements making PET scanners even more sensitive and providing greater image uniformity (especially as compared to SPECT). The increased adoption of PET over SPECT in cardiology has also been 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

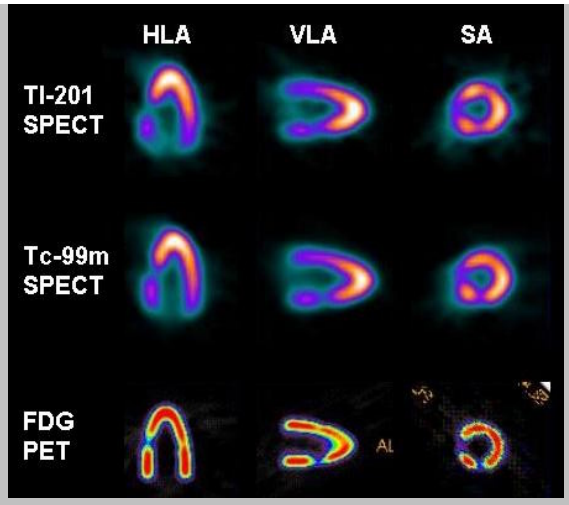


SOURCE: TriMark Publications, May 2011 *Nuclear CardiologyMarkets;Trends, Industry Participants, Product Overviews and Market Drivers.* PlanClear Company "Quarterly Update 2010".

Bio-Tech Systems, a healthcare market research firm specializing in medical imaging, notes in a recent report that U.S. sales of PET scanners fell 21% from 2008 to 2009 as a result of uncertainties over reimbursement and excess capacity. International sales were similarly soft due to a weak capex environment. Bio-Tech Systems expects worldwide PET scanner sales to significantly firm up, however and projects annual growth of about 10% from 2009 through 2017. PET procedure volume is also on the rise, growing 9% in 2009 despite the double-digit drop in scanner sales. While a portion of this growth can be attributed to cuts in (per-procedure) reimbursement, prompting greater utilization, greater use of PET for cardiac applications has arguably been the greatest catalyst.

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.



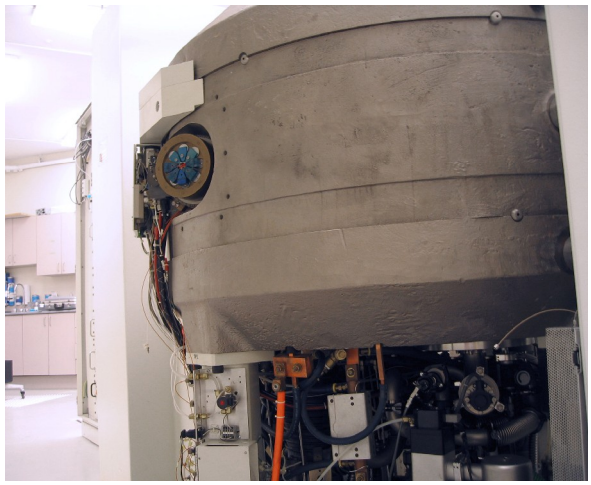
Dr. Josef Machac, *PET Myocardial Perfusion Imaging*: Image uniformity is by far the most important property of PET imaging for cardiac imaging. Coincidence detection allows more effective correction for non-uniform attenuation than for SPECT imaging. Non-uniform attenuation in the chest results in multiple 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.

CARDIAC PET REIMBURSEMENT

The Centers for Medicare and Medicaid Services (CMS) have approved the use of PET to test for "myocardial viability" as a "primary or initial diagnosis, or following an inconclusive SPECT prior to revascularization" using an FDG tracer. PET is also covered for non-invasive imaging of the perfusion of the heart using Rubidium 82 or N-13 as tracers.

CMS provides PET cardiac imaging reimbursement for a "professional" component and separately for a "technical" component (the technical component accounts for the vast majority of the total reimbursement). The professional component relates to the services provided by the attending physician while the technical component relates to use of the scanner. From 2010 to 2011 CMS reduced reimbursement of the technical component for cardiac PET by 23% (from $1,429 to $1,107 per scan) effective January 1, 2011. This is in contrast to reimbursement of SPECT MPI, which was cut by less than 2% from $773 to $760. CMS recently announced final reimbursement changes for 2012. These include cardiac PET (technical) reimbursement being slightly trimmed (~6%) from $1,107 to $1,038 and SPECT MPI cut 12% from $760 to $672.

We note that while CMS cut reimbursement for cardiac PET significantly more than for SPECT (27% vs. 13%) from 2010 to 2012, PET reimbursement remains almost $400 more than SPECT. Which, despite the higher cost of PET, could still offer a reasonable incentive to use PET over SPECT for cardiac imaging (especially when considering the many potential advantages of PET versus SPECT - including better patient care).

However, reduced reimbursement means imaging centers will need to increase utilization to cover the cost of a (very expensive) PET scanner - but greater scrutiny by CMS on what is appropriate use (sparked by suspicions of imaging overutilization), means imaging centers need to broaden their scope of approved indications. The silver bullet for PET imaging centers to this issue could be novel tracers - which could be an additional catalyst to long-term growth of new cardiac agents, potentially significantly outpacing the ~14% CAGR estimated by Bio-Tech Systems for FDG. This could be a very significant boon for a company like FluoroPharma, with novel agents that are expected to directly address increasing the scope of value-added PET cardiac imaging procedures.

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.

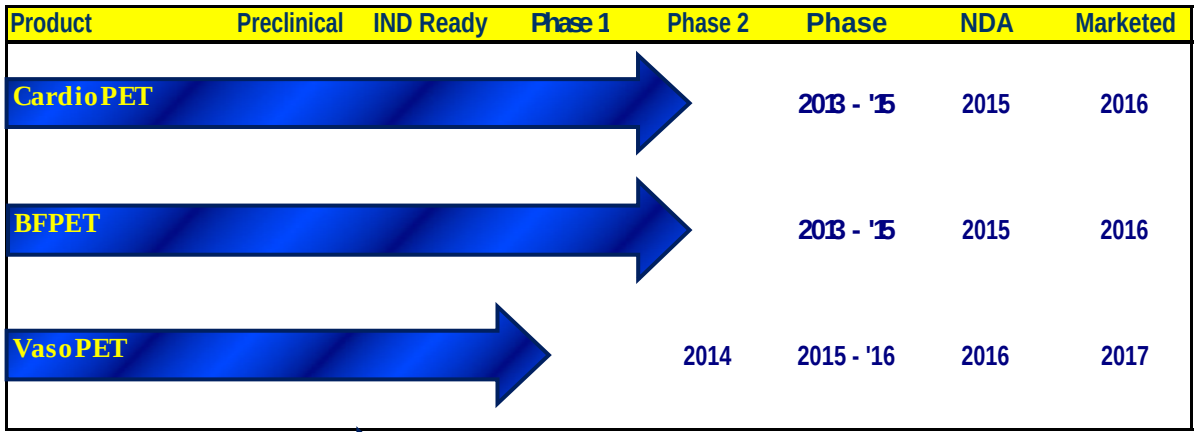
PRODUCTS

FluoroPharma's current focus is on three separate cardiac molecular imaging pharmaceuticals, two of which (CardioPET and BFPET) are in clinical-stage. CardioPET entered phase II in Q1 2012 with BFPET expected to start phase II trials later in 2012. The third candidate (VasoPET) 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 five 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 12/31/2011 (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. Per FPMI's 10-K filed on 3/16/2012 the company expects phase II trials for BFPET to begin in 2012. Based on current expected timelines, we believe phase II trials might be completed by sometime in 2013. If all goes to plan, phase III trials could wrap up and an NDA filed by the end of 2015. This potentially puts BFPET on the U.S. market by 2016.

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.

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 has completed phase I trials and in March 2012 FluoroPharma announced the initiation of phase II trials. The company signed a letter of intent with SGS Life Sciences to provide clinical research services for phase II trials of CardioPET. The Belgian-based trial will be 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 with results anticipated in 2H 2012. Enrollment is expected to consist of between 30 and 100 patients with known stable chronic coronary artery disease that can not undergo stress testing.

If all goes to plan phase II will wrap up in 2013 and phase III completed and an NDA filing potentially happening by the end of 2015. U.S. launch could potentially happen by 2016.

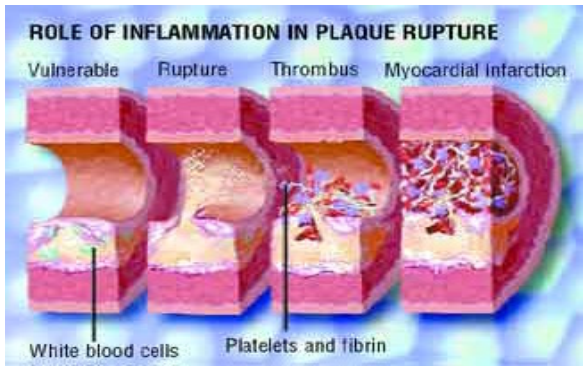
Phase I trials (used to assess safety / tolerability) consisted of 6 patients with diagnosed CAD and 15 normal healthy volunteers (i.e. - control group). Phase I testing completed in April 2007 and demonstrated CardioPET was safe with no patients experiencing any adverse events.

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. Eventual FDA approval and subsequent launch is likely to be at least six years away (~ 2017+).

MARKETS

Bio-Tech Systems notes in a June 2011 report that U.S. sales of SPECT and PET radiopharmaceuticals reached $1.2 billion in 2010 and are expected to grow to $6.0 billion by 2018 (~22% CAGR). They expect the majority of this growth to come from the introduction of novel radiopharmaceutical products for new indications and applications (including Alzheimer's, Parkinson's and new oncology and cardiac applications), as well as higher radiopharmaceutical prices.

FluoroPharma's target market, cardiac PET radiopharmaceuticals, is a subset of this larger market. Bio-Tech Systems estimates that U.S. sales of FDG (i.e. - current most commonly used PET cardiac tracer) will grow at about 14% annually from $300 million in 2009 to $880 million in 2017. They attribute this expected growth to the introduction of novel cardiac tracers as well as the continued increase in the volume of cardiac procedures. Specifically, Bio-Tech Systems notes, "PET perfusion agents for cardiology will offer capabilities for diagnosing complex cases and encourage more physicians to adopt PET for cardiology applications."

FluoroPharma's PET cardiac agents are expected to capitalize on the health care industry's rapid shift towards personalized medicine by providing physician's with more information relative to the extent of disease progression and related risk. This not only should afford better patient outcomes through early and targeted (i.e. - most effective) treatment, it also should reduce overall healthcare costs by reducing unnecessary, inefficient and unsuccessful therapies.

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 60% share of the evaluable cardiovascular PET market.

Based on these assumptions, FluoroPharma estimates that BFPET could capture about 1% of the total market for MPI radiopharmaceuticals in the first full year after launch (i.e. - possibly ~2016/2017) and will account for about 7% of the market five years following launch (i.e. - possibly ~ 2021/2022) - 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 $30 million in the first full year after launch and ~ $200 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 2 million patients with chronic CAD that can not undergo exercise stress testing, the 1.5 million people that could benefit from cardiac viable assessment, and a portion of the 10 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. For the myocardium viability indication, FluoroPharma believes CardioPET could attain about 10% market share within five years of launch. Based on these assumptions, the company believes that within the third year of launch, CardioPET could be used in approximately 350k procedures, growing to 750k procedures in year five post-launch. This could equal a potential revenue opportunity to FluoroPharma of approximately $100 million in the third year (i.e. - ~2019/2020) and $200+ million in the fifth year (i.e. - ~2021/2022) after launch.

VasoPET: *Vulnerable Plaque*
VasoPET is expected to be able to identify the presence of inflammation and vulnerable plaques, the rupture of which could increase the risk of heart attack or stroke. The target market for VasoPET is expected to be those patients that have been diagnosed with ischemia through conventional exercise stress testing and specifically those that have already experienced an acute cardiac event such as a heart attack or stroke. VasoPET could be ideal in helping determine effective treatment to this patient population including appropriate medication and dosage. This target market represents approximately 30% of the total CAD patient population, or about 4 million people. VasoPET could also have utility as a first line diagnostic for atherosclerosis, which would expand its potential target market to an additional ~ 50 million people. Based on estimated penetration rates of these target markets (0.6% of the atherosclerosis market and 10% of the post cardiac event market, five years after launch), FluoroPharma believes that VasoPET could be used in approximately 100k PET scans in the first full year of launch, growing to 300k and 500k scans in the third and fifth year (post-launch), respectively. This implies a potential revenue opportunity of ~$40 million in year 1 (2017/2018), $120 million in year 3, and $200 million in year 3 (2022/2023).

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 will be 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. 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 is not clear if 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
As of their most recent reporting period (12/31/2011) FluoroPharma had $3.3 million in cash and equivalents, basically flat from the end of Q3 and benefitting from approximately $940k in net ($1.01 million gross) proceeds raised from the sale of equity during the most recent quarter. Cash used in operations was $2.3 million in 2011 including $711k in Q4.

In addition to the Q4 2012 capital raise, concurrent with and shortly following the May 2011 reverse merger, FluoroPharma raised a total of $4.6 million (net proceeds) through the sale of common stock ($3.2MM) and convertible preferred stock ($1.4MM).

We believe the cash balance may possibly be enough to fully fund completion of phase II clinical trials for BFPET and CardioPET (which are expected to finish before VasoPET phase II trials), which in aggregate, we estimate will cost approximately $1.5 million. If and when FluoroPharma needs to raise additional operating capital, potential funding sources include the additional sale of common and/or convertible preferred stock.

Convertible Preferred Stock
As of 12/31/2011 9/30/2011 there were 3.5MM authorized Series A convertible preferred shares authorized and 1.92MM shares outstanding. Each share accrues dividends at 10% and is convertible at any time into common stock at the conversion price of $0.83.

STRATEGY / OUTLOOK

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

CLINICAL TRIALS

Both BFPET and CardioPET have completed phase I testing. FPMI announced in early March that they signed a letter of intent with SGS Life Sciences to act as the CRO for phase II trials of CardioPET, the initiation of which is expected to be imminent. The trial will be conducted at two sites in Belgium with results anticipated in 2H 2012. The trial will be open label and designed to assess safety and performance of CardioPET compared to stress echocardiography, myocardial perfusion imaging (MPI) and angiography. Per the most recent 10-K (filed 3/16/2012), enrollment is expected to consist of between 30 and 100 patients with known stable chronic coronary artery disease that can not undergo stress testing.

FPMI expects phase II trials for BFPET to begin later in 2012. The specific design / protocol of the phase II BFPET trials has yet to be announced, although, similar to the phase II CardioPET protocol, the comparator (i.e. - control) is expected to be the standard of care. Location of the trial sites will likely need to consider tracer sourcing / manufacturing as FluoroPharma currently lacks these inputs. The trial design will be announced prior to the commencement - until then we estimate BFPET enrollment will also be approximately 50 patients.

As noted earlier, 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. Current development timelines imply the earliest VasoPET would likely make it to market will be 2017. 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 BFPET and CardioPET could start sometime in 2013 and possibly wrap up during 2015. 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 BFPET and CardioPET could be approved for sale in the U.S. sometime in 2016.

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 $270 million. As this may be more of a better-case scenario, we think it is appropriate to apply a significant (50%) haircut. We use a 2.5x price/sales multiple to estimated (i.e. - ballparked) 2019 revenue of $135 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 $45 million, or about $2.00 / share.

We have also built a DCF model through 2022 which also supports a valuation of approximately $2.00. Key inputs to our DCF model are revenue commencing in 2017 and growing to around $300 million in 2022 and a ~19% cash flow discount rate (which again, reflects inherent risks of a FPMI's development-stage status). Our DCF model calculates a valuation of $2.16.

Depending on the progression, success and timeliness of product development and related likelihood of ultimate FDA approval / commercialization, it may be appropriate to adjust 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 $2.00/share. Based on the current share price of $0.80, 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 four to five 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.

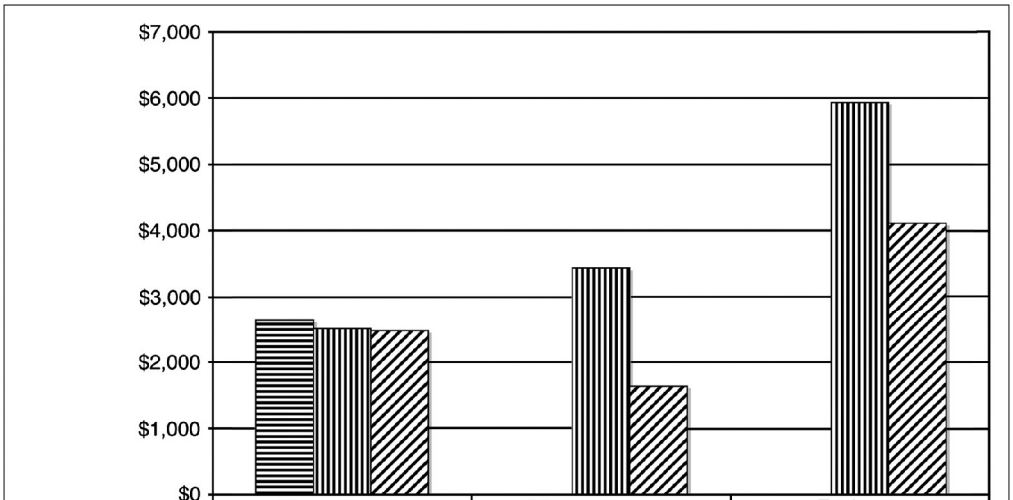
APPENDIX

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

David R. Elmaleh, PhD – *Chairman, Director and Chief Scientific Advisor*
Dr. Elmaleh, the scientific founder of FluoroPharma Inc., is an Associate Professor at Harvard Medical School and the Director of Contrast Media Chemistry at the Massachusetts General Hospital (MGH). He is an inventor of three drugs that are in use in man or in late stage clinical trials including: The radiopharmaceutical preparation of (2FDG) which has been used in over a million PET imaging procedures, Beta-methyl modified fatty acid (BMIPP) a commercially successful cardiac SPECT agent, and Altropane which has completed phase 3 clinical trials. His recent work has included extensive research on imaging compounds to improve the speed and effectiveness of cardiovascular disease diagnosis which constitutes the technology licensed from MGH to FluoroPharma. He is a co-author on over 120 publications and an inventor of over 40 issued and pending patents in a range of disciplines, including molecular imaging and pharmaceuticals. Dr. Elmaleh is a recipient of numerous National Institute of Health (NIH) and DOE awards, and has participated as a reviewer for the NIH. He is the Scientific Founder of Biostream (changed name to Molecular Insight Pharmaceuticals) and several other start-ups. He holds a BSc in Physics and Chemistry, and an MS and PhD in Chemistry from the Hebrew University of Jerusalem.

Thijs Spoor – *Director, 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.

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.

PROJECTED INCOME STATMENT

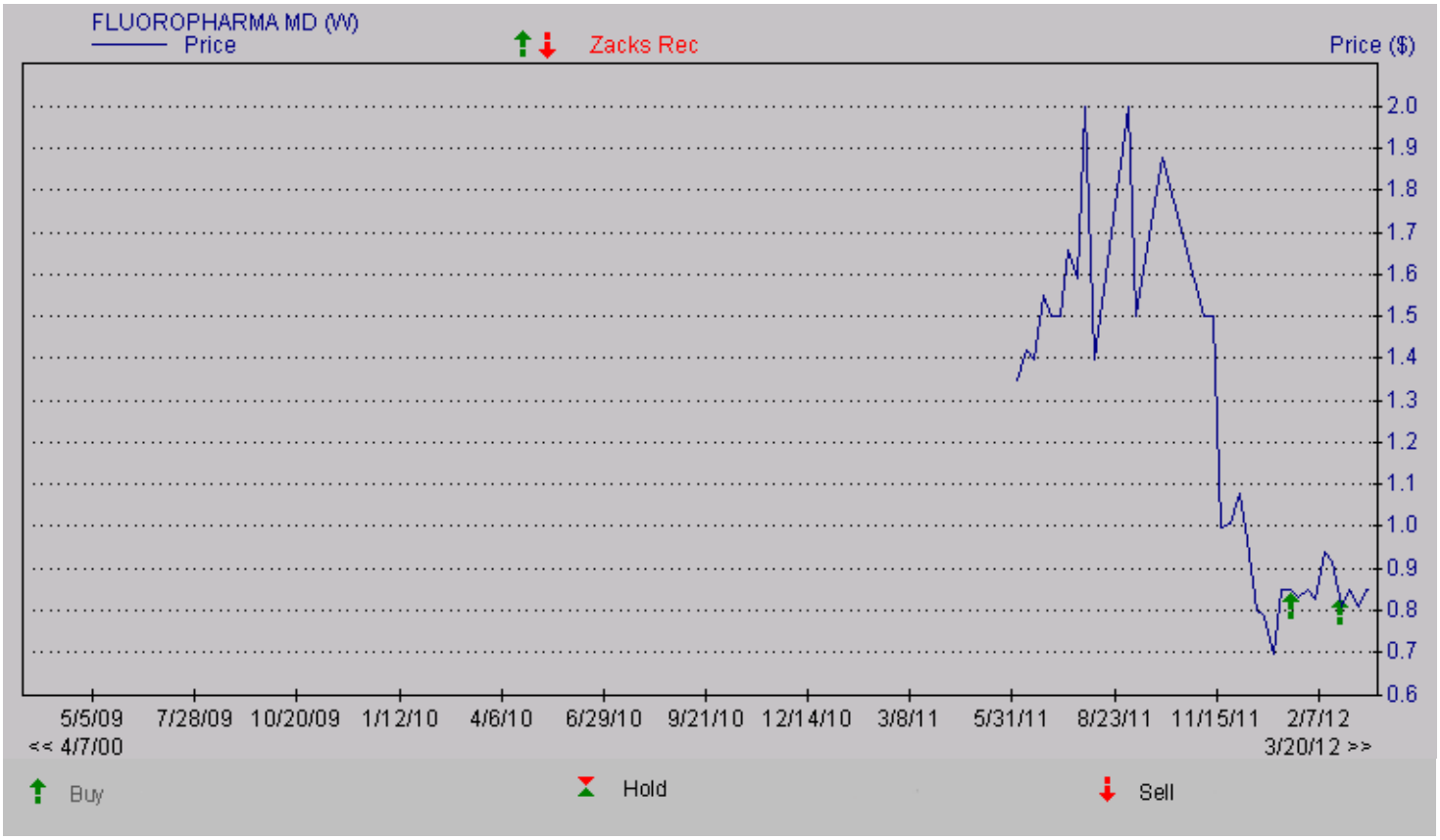
FluoroPharma Medical, Inc.

	2011 A	Q1 E	Q2 E	Q3 E	Q4 E	2012 E	2013 E	2014 E	2015
CardioPET	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	
BFPET	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	
VasoPET	**$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**	**$0.0**
YOY Growth	-	-	-	-	-	-	-	-	
Cost of Goods Sold	$0	$0	$0	$0	$0	$0	$0	$0	$0
Gross Margin	-					-	-	-	
Sales, General & Admin	$2.7	$0.5	$0.5	$0.5	$0.5	$2.0	$2.0	$2.3	$2.5
% SG&A	-					-	-	-	
Research & Development	$0.6	$0.5	$0.4	$0.4	$0.5	$1.8	$5.0	$8.0	$10.0
% R&D	-					-	-	-	
Depreciation & Amortization	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($3.4)	($1.0)	($0.9)	($0.9)	($1.0)	($3.8)	($7.0)	($10.3)	($12.5)
Operating Margin	-					-	-	-	
Interest & Other Income	($0.0)	($0.0)	($0.0)	($0.0)	($0.0)	($0.0)	($0.0)	($0.0)	($0.0)
Pre-Tax Income	($3.4)	($1.0)	($0.9)	($0.9)	($1.0)	(3.9)	$7.0	$10.3	$12.5
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	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	($4.4)	($1.1)	($1.0)	($1.0)	($1.1)	($4.0)	($7.3)	($10.6)	($12.8)
Net Margin	-					-	-	-	
Reported EPS	**($0.25)**	**($0.05)**	**($0.04)**	**($0.04)**	**($0.04)**	**($0.18)**	**($0.23)**	**($0.24)**	**($0.25)**
YOY Growth	-					-	-	-	
Weighted Ave. Shares	17.7	22.0	22.5	23.0	23.5	22.8	32.0	44.0	52.0

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