Molecular Imaging to Enhance Patient Outcomes in Cardiovascular Disease
Forward-Looking Statements

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FluoroPharma (FPMI) Overview

• Developing the next generation of cardiac imaging
  • Applying PET to unmet needs in heart disease management

• PET (Positron Emission Tomography) provides insight at the molecular level
  • Molecular Imaging illuminates biochemical processes with high resolution
  • Superior to current standard, SPECT (Single Photon Emission Computed Tomography)

• Cardiologists have embraced Molecular Imaging
  • Provides information critical to optimal decision making

• They hunger for improved methods such as PET to answer questions for which current technologies fail
FPMI PET Cardiac Imaging Portfolio

• Three unique PET assets in mid-late stage development
  - Revenue potential of $500 million - $1 billion each

• mFBG (being acquired)
  - Phase 3 ready in a FDA-sanctioned program
  - Revenue in 24-30 months for orphan oncology indication
  - Supplemental, much larger cardiac indication to follow
    - Support decisions on cardiac device placement, a major unmet need

• CardioPET
  - Phase 2B ready
  - Initial indication: difficult to diagnose patients in early heart failure
  - Additional applications in other areas of heart disease
  - Unique mechanism of action provides metabolic as well as blood flow information
• BFPET
  • Starting Phase 2 studies in 2H17
  • Assessment of mitochondrial membrane integrity
  • Potential electrical conductivity heart mapping
  • May enable improved efficiency and effectiveness for electro- 
    ablation, a growing therapy for cardiac arrhythmias

• Low risk programs from developmental, regulatory and 
  commercial perspectives

• Strong IP provides robust global coverage
Experienced Management Team and Advisors

**Thomas H. Tulip, Ph.D.** President and CEO
- Healthcare executive with greater than 25 years medical imaging industry experience
- Recognized medical imaging leader
- Former Executive at Navidea, Alseres, Lantheus and Bristol-Myers Squibb
- Led development, commercialization and internationalization of Cardiolite

**Edward L. Lyons, Jr.** Vice President, Development
- Healthcare professional with >25 years nuclear cardiology experience
- Led the nuclear cardiology portfolio at GE Healthcare
- Led clinical development, marketing and medical affairs at DuPont Pharma, Bristol-Myers Squibb and GE Healthcare

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**Scientific Advisory Board**

**H. William Strauss, MD**
- Pioneer of Cardiac Nuclear Medicine; Attending Physician Emeritus of Molecular Imaging at Memorial Sloan Kettering Cancer Center, New York

**Gary Heller, MD, PhD**
- Morristown Medical Center; Past President of the American Society of Nuclear Cardiology, Fellow of the American College of Cardiology

**Heinrich Schelbert, MD**
- Professor of Molecular & Medical Pharmacology, UCLA School of Medicine

www.FluoroPharma.com
Why Focus on Heart Disease?

1 in 3

...People will die of heart disease

Every 34 seconds

...A new heart attack occurs

Every 3 seconds

...A cardiac perfusion scan is performed
### Nuclear Cardiology: Dramatic Growth

<table>
<thead>
<tr>
<th>Year</th>
<th>Studies Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1990</td>
<td>1 Million US Blood Flow Studies</td>
<td></td>
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<tr>
<td>1991</td>
<td>Cardiolite™ introduced</td>
<td>- $^{99m}$Tc SPECT* agent</td>
</tr>
<tr>
<td>2005</td>
<td>~7.5 Million US Blood Flow Studies</td>
<td>- $^{99m}$Tc agent US end-user revenue: $1.3B ~ $70/dose*</td>
</tr>
</tbody>
</table>

At today’s PET pricing, this market would exceed $20B

Cardiologists embraced technology

Nuclear Perfusion Studies 1996 - 2008
Nuclear Cardiology Today

• Approximately 7.5 million US studies

• Standard of care remains SPECT
  • Despite shortcomings in resolution, quantification and radiation exposure

• Growing percentage of patients underserved

• $^{82}\text{Rb}$ is the pioneer (1991) cardiac PET imaging agent
  • 4% overall share; Est. $130$ million revenue
  • Limited use due to
    • 75 second half-life
    • Requires $40$ thousand/month; cumbersome equipment
    • Only applicable in very high volume practices
    • Supply chain issues
    • Safety concerns
BFPET images demonstrated **higher resolution** than SPECT

<table>
<thead>
<tr>
<th>SPECT</th>
<th>BFPET</th>
</tr>
</thead>
<tbody>
<tr>
<td>On SPECT this patient appeared to have a defect...</td>
<td>...while BFPET clearly and correctly showed that patient’s heart was healthy</td>
</tr>
</tbody>
</table>

Source: Results of investigator-sponsored trial at PLA 301 Hospital in Beijing, China.
PET: Better than SPECT

<table>
<thead>
<tr>
<th>Higher resolution</th>
<th>Higher diagnostic and prognostic accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Easier to interpret</td>
<td></td>
</tr>
<tr>
<td>• Older agent artifacts eliminated</td>
<td></td>
</tr>
<tr>
<td>• More readily quantifiable images</td>
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</table>

<table>
<thead>
<tr>
<th>Lower radiation exposure</th>
<th>Improved outcomes, decreased risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Patients and staff</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Established Supply Chain</th>
<th>Easy, secure access to doses and camera time</th>
</tr>
</thead>
<tbody>
<tr>
<td>• More than 100 distribution centers and 3000 PET cameras for $^{18}$F agents</td>
<td></td>
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</tbody>
</table>
New Guidance for PET Cardiac Imaging

Important Properties of Myocardial Perfusion PET:

1. High diagnostic accuracy
2. Consistent high image quality
3. Low radiation exposure
4. Short protocols
5. Quantification of blood flow
6. Strong prognostic power

Clinical Indications:

1. Preferred test for patients unable to exercise
2. Recommended test for patients with active CAD, plus 1 or more of:
   a) Prior poor quality study
   b) Body characteristics like obesity
   c) High-risk patients
   d) Young patients with established CAD
   e) Blood flow is a needed adjunct
In this head-to-head comparative study of 208 adults, sensitivity was 90% for coronary computed tomography angiography, 57% for single-photon emission tomography, and 87% for positron emission tomography, whereas specificity was 60% for coronary computed tomography angiography, 94% for single-photon emission tomography, and 84% for positron emission tomography.

**Positron emission tomography exhibited the highest diagnostic accuracy compared with single-photon emission tomography and coronary computed tomography angiography.**
# Cardiac Nuclear Imaging Landscape

<table>
<thead>
<tr>
<th>SPECT</th>
<th>Properties</th>
<th>Utility</th>
<th>Cost</th>
<th>Image Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>99mTc SPECT (Cardiolite, Myoview)</td>
<td>• 140 KeV gamma</td>
<td>• Broad application, patient populations underserved</td>
<td>• Low ($100)</td>
<td>• Low</td>
</tr>
<tr>
<td></td>
<td>• 6 hour half-life</td>
<td>• “Kit” products, unit dose</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>• Long shelf life</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>• Requires Mo-99 generator</td>
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<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PET</th>
<th>Properties</th>
<th>Utility</th>
<th>Cost</th>
<th>Image Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rubidium-82 (CardioGen, Ruby-FILL)</td>
<td>• Potassium analog</td>
<td>• Image quality &gt; 99mTc</td>
<td>• High ($40K per month, procedure dependent)</td>
<td>• Medium</td>
</tr>
<tr>
<td></td>
<td>• 1.2 min half-life</td>
<td>• Short half-life mandates pharmacologic stress only</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 8.6 mm range</td>
<td>• Strontium generator</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>CardioPET (18F FCPHA)</th>
<th>Properties</th>
<th>Utility</th>
<th>Cost</th>
<th>Image Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Fatty Acid analog</td>
<td>• Myocardial metabolism and viability</td>
<td>• Intermediate- ($1500/ injection)</td>
<td>• High</td>
</tr>
<tr>
<td></td>
<td>• 109 min half-life</td>
<td>• Identify CAD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 1.03 mm range</td>
<td>• Independent of stress procedure</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Reimbursement codes in place</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Cyclotron production with commercial distribution</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
- Phase 3 ready $^{18}$F PET development candidate
  - Best-in-class agent
- Initial pediatric orphan cancer indication
  - IND submitted
  - Fast track to pioneer approval
  - Revenue in 24-30 months
- Following indication for large cardiac application
- Structured acquisition from Ground Fluor Pharma (GFP)
- Large ancillary revenue opportunity
  - Sale of Pediatric Review Voucher
Imaging with mFBG provides significantly better lesion identification versus

$^{123}$I-mIBG SPECT, current standard of care
Conclusion: Preliminary data show that $^{18}$F-MFBG imaging is safe and has favorable biodistribution and kinetics with good targeting of lesions. PET imaging with $^{18}$F-MFBG allows for same-day imaging of [neuroendocrine tumors] (NETs). $^{18}$F-MFBG appears highly promising for imaging of patients with NETs, especially children with neuroblastoma.
mFBG Status

- $^{18}$F PET performance better than $^{123}$I SPECT, enabling better patient management ($^{18}$F-mFBG vs $^{123}$I-mIBG)
  - 4-fold improvement in target to background
  - Improved accuracy in identifying small lesions
  - Improved safety and patient comfort/convenience
  - Improved laboratory efficiency
  - Imaging at 2 rather than 24 hours

- **Proof of concept human study at Memorial Sloan Kettering ongoing**
  - Largest center in the US for these patients
mFBG Revenue Projection

Target price point of $3750

• Fully reimbursable; PET oncology coverage: $3750
• Lower than mIBG price: $4850
• SPECT code: $1140
• Significant economic incentive for hospitals, who lose $3710 per dose on mIBG

Barriers to Entry

• Unique proprietary chemistry
• Orphan drug exclusivity
• Partnership with leading centers
mFBG Revenue Opportunity

Pediatric review voucher

• FDA program to incentivize pediatric orphan drug development
• Provides FDA expedited review voucher on initial approval
• Voucher can be sold
  • Sale range: $75 to 350 million

mFBG qualifies
• Voucher availability 2020
Repurposing mFBG for Cardiology: Heart Failure

• US Heart Failure prevalence over 5 million

• Annual care system cost more than $39 billion

• Expensive Internal Cardiac Defibrillators (ICD) are commonly used; major system cost
  • $50 thousand for ICD placement and $16 thousand annual maintenance

• Annual new US implants: 434 per million population or 140,000

• More than 30% of implants are not needed: They never fire
  • Unnecessary expense and invasive trauma


- Application: Identification of those at risk for cardiac death, disease progression, or cardiac arrhythmia, targets for ICD placement

- Very low market penetration

- High pricing/inadequate reimbursement

- Clinical trials poorly designed; marginal technical performance

- 5000 scans per year at $3850 per dose for $15 Million revenue
  - Price now raised to $4850 per dose

- CMS reimbursement for “myocardial sympathetic innervation” $1140
  - Large customer loss per dose
Potential for $^{18}$F-mFBG in Heart Failure

- Improved patient management
- Much better performance than $^{123}$I SPECT
  - Improved target to background
  - Improved patient flow and convenience
  - Decreased radiation dose to patients
  - Ability for quantitative analysis
- Improved economics for facility and patient
  - PET level reimbursement
- US revenue potential more than $300$ million
Development of $^{18}$F-mFBG in Heart Failure

- Initially focus resources on pioneer oncology indication
- Work with Mt. Sinai and Sloan Kettering for NIH funding of Proof of Concept (PoC) study
- Plan Phase 3 program to follow PoC results and NDA submission
- Seek accelerated approval via sNDA route
CardioPET: Excellent Phase 1 Results

Fatty acid analog that detects regions of metabolic insufficiency

PHASE 1 TRIAL COMPLETED
– Included 6 CAD* patients

Results:
• CardioPET safety: no adverse events detected
• Quality of CardioPET images visually superior to those of SPECT

Scan identifies areas of dead tissue and diminished blood flow in a patient with previous heart attack

*CAD = Coronary Artery Disease
CardioPET: Encouraging Phase 2A Results

Fatty acid analog that detects regions of metabolic insufficiency

PHASE 2A TRIAL: RESULTS

• Well tolerated, no adverse events related to study drug
• CardioPET images were of superior quality vs. SPECT
• CardioPET resting studies identified CAD without exercise in certain subjects

CardioPET study correctly demonstrates regional decrease in blood flow
CardioPET Images Superior to SPECT Images

Comparison of Image Quality, PET early (10 min) and late (50 min) with Rest and Stress SPECT: Excellent/Good and Fair/Poor

Percent

\[ p = < .01 \text{ for PET vs. SPECT} \]

ASNC 21st Annual Meeting, September 24, 2016

www.FluoroPharma.com
CardioPET Superiority to Standard of Care

Example: Normal CardioPET
59 year old female patient with typical angina, hypertension
Angiogram = no CAD

Exercise Tc-99m SPECT

Early
Late

Exercise PET

04-004
48 y/o M, DM, HTN, lipids, NYHA II
70% RCA, 30% LCx, 15% LAD

Stress Tc-99m
Rest Tc-99m
Rest PET Early
Rest PET Late

False Positive SPECT, CardioPET Correct; Unnecessary, expensive, invasive catheterization would have been avoided

Rest-only CardioPET positive for CAD, comparable outcome required two injections and images for SPECT
CardioPET Summary

- Has unique physiologic mechanism of action
- Provides assessment of metabolism and blood flow
- Is superior to SPECT in image quality, and PET quantifiability
- 75% of the resources required in the today’s standard procedure could be eliminated without loss of diagnostic accuracy by using Rest-only imaging
- Is poised to move into Phase 2B to validate this finding
- Has a range of additional potential indications
- PET cardiac reimbursement codes in place
BFPET: Phase 1 Results; Phase 2 Plan

Phase 1 trial completed (12 Normal Healthy Volunteers)
• 6/12 whole body scans/dosimetry
• No adverse events
• Rapid extraction, stable heart uptake

Phase 2A trial: Poised to initiate
• To evaluate diagnostic performance in suspected coronary disease; evaluate potential for electrophysiology applications
• Primary site opened for recruitment

Tracks coronary blood flow and cell membrane integrity

BFPET/CT images in a 60-year old female subject
BFPET Summary

• Atrial Fibrillation (AF) and Ventricular Tachycardia (VT)
  • Associated with increased mortality in individuals with other cardiovascular conditions: Heart Failure, Heart Attack and Stroke

• Invasive ablative therapies
  • Increasing with growing incidence and prevalence

• BFPET may map mitochondrial (therefore electrical) integrity of the heart
  • Non-invasively
  • More precision in, and better results from, ablative techniques

• Entering Phase 2 human validation initiated in 2H17
  • Funding offset by MGH grant award from NIH
<table>
<thead>
<tr>
<th>Year</th>
<th>Milestones</th>
</tr>
</thead>
</table>
| 2018 | • mFBG acquisition  
      • mFBG Phase 3 (P3)  
      • CardioPET P2B and BFPET P2A startups  
      • mFBG and BFPET grant awards  
      • mFBG licensing |
| 2019 | • CardioPET P2B completion  
      • CardioPET licensing  
      • mFBG cardiac studies initiated  
      • mFBG P3 completion  
      • CardioPET P3 plan |
| 2020 | • CardioPET P3 initiation  
      • -mFBG NDA submission and approval  
      • Pediatric Review Voucher award; monetization  
      • mFBG cardiac studies results |
• Activate team of experienced colleagues – Virtual, reliant on contracted subject matter experts

• Acquire world-wide rights for mFBG from GFPharma

• Initiate and complete mFBG Phase 3 program; gain pioneer FDA approval and monetize Pediatric Review Voucher

• Initiate and complete CardioPET Phase 2B program

• Prepare CardioPET Phase 3 program

• Nurture mFBG cardiac PoC grants and studies

• Initiate and complete BFPET Phase 2A; initiate Phase 2B

• Generate non-dilutive funding from licensing and grants
## Non-dilutive Near Term Licensing

<table>
<thead>
<tr>
<th>License Description</th>
<th>Year</th>
<th>Amount ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>mFBG Licenses in Asia and EU**</td>
<td>2H18</td>
<td>4</td>
</tr>
<tr>
<td>CardioPET License for Japan</td>
<td>Post Phase 2B, 1H19:</td>
<td>5</td>
</tr>
<tr>
<td>CardioPET License for EU</td>
<td>1H19</td>
<td>3</td>
</tr>
<tr>
<td>CardioPET for China and Canada</td>
<td>2019 - 20</td>
<td>1</td>
</tr>
<tr>
<td>BFPET License for EU</td>
<td>2H19</td>
<td>3</td>
</tr>
<tr>
<td>BFPET License for Japan</td>
<td>2H19</td>
<td>5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>$21</strong></td>
</tr>
</tbody>
</table>

*Estimated based on recent transactions*

**mFBG oncology focus; cardiac indication licensing in major geographies after initial studies complete**
FPMI is seeking to raise $12 million to

- Build on $2 million lead from strategic investor and potential $3 million option from second strategic
- Acquire world-wide mFBG rights
- Initiate and complete mFBG Phase 3 in oncology and gain FDA approval in 24-30 months
- Advance CardioPET through Phase 2B in next year
- Prepare for CardioPET Phase 3
- Nurture NIH-funded PoC study of mFBG in cardiology
- Initiate a small Phase 2 program for BFPET for a novel cardiac arrhythmia application
Molecular Imaging to Enhance Patient Outcomes in Cardiovascular Disease