Introduction

The Company, based in Texas, was formed in October 2018, bringing together a group of highly skilled individuals with decades of collective experience in several key facets of the radioisotope and radiopharmaceutical supply chain. Their areas of expertise include production, development, supply, regulatory aspects and penetration of both the retail and wholesale markets.

Recent high-profile corporate acquisitions and share offerings have created renewed interest in the radiopharmaceutical industry. The recent takeovers of Endocyte and Advanced Accelerator Applications (AAA) by Novartis, for $2.1B and $3.9B respectively, have raised the profile of radiopharmaceutical ‘theranostic’ (products that act as both a diagnostic and a therapeutic agent) products and radiopharmaceuticals in general. Both entities are either producing or developing unique ‘theranostic’ products based on the isotope Lutetium-177. The Company intends to supply Lu-177 using proprietary, non-conflicting IP, owned by the company, and has a preferential relationship with a raw material supplier, a company that has a guaranteed supply of Ytterbium-176 (Yb-176), the precursor to Lu-177.

In addition, the company intends to supply a broad portfolio of diagnostic and therapeutic isotopes from an internal production capability with value-added capture from sales through an in-house nuclear pharmacy. The strategic inclusion of CMO and CDMO services ensures that the business will be well placed to capitalize on new, as well as existing, opportunities in the radiopharmaceutical market.

Opportunities in the radiopharmaceutical sector to achieve cost savings and gain a competitive advantage have been identified by the group. Specifically, by integrating the majority of nuclear medicine supply chain components under one roof and having the capability to foster the development of new products, the company will be well placed to capture significant revenues and enhance the growth of this niche-market as a whole. Current entities in the nuclear medicine industry are focused on one or two of these components.

Target Radiopharmaceutical Markets

- GMP Active Pharmaceutical Ingredients
  - Generic Single Photon Emission Computer Tomography (SPECT) & Positron Emission Tomography (PET) Diagnostic agents (e.g. In-111, I-123, Ga-67, Tl-201, Cu-64, Zr-89, Tc-99m, Ga-68/Ge-68)
  - Theragnostic (e.g. I-131, Lu-177)
  - Targeted Alpha therapies (e.g. Ac-225, Ac-225/Bi-213)
- Nuclear Pharmacy
- Contract Manufacturing
- Contract Development (non-GMP Pre-clinical & PI studies, GMP PII/III trials)

Investment & Company Highlights

i. Status & Required Funding

- Up to $15,700,000 staged funding required
- Brand new GMP facility, full CMO/CDMO & production capabilities

<table>
<thead>
<tr>
<th>Facility Purchase</th>
<th>Land (PIW Metroplex) $1,400,000</th>
<th>Facility $9,800,000</th>
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<tbody>
<tr>
<td>Initial Working Capital</td>
<td>$4,500,000</td>
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<table>
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<tr>
<th>Capital Expenditure</th>
<th>Cyclotron $5,500,000</th>
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<tr>
<td>Manufacturing Equipment $3,500,000</td>
<td></td>
</tr>
<tr>
<td>Linear Accelerator (Upgrades) $3,500,000</td>
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<tr>
<td>Linear Accelerator Targets $800,000</td>
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FINANCE TOTAL $12,500,000
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- In-House Pharmacy
- Equipment to be purchased with financing
- Company generating revenues (Q2 2019) in advance of facility build
- Supply agreement in place with key supplier and initial customer (estimated preliminary gross orders $450,000/year)
- Current customer servicing Asian & Latin American markets
- Company in discussion with several key potential customers (15 NDAs executed, 1 MOU for contract manufacturing Q1 2020)
- Existing company assets of $20-25m

II Operational Financial Estimates (Years 1&2)

<table>
<thead>
<tr>
<th>Item</th>
<th>YEAR 1</th>
<th>YEAR 2</th>
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<tbody>
<tr>
<td></td>
<td>Q1</td>
<td>Q2</td>
</tr>
<tr>
<td>Investment/Finance</td>
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<tr>
<td>Gross Revenues</td>
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<td>CAPEX Payments</td>
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<td>Opex</td>
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<tr>
<td>Total</td>
<td>($3,994,454)</td>
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<tr>
<td>Cash Reserve</td>
<td>$60,418</td>
<td>($592,151)</td>
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<tr>
<td>EBITDA</td>
<td>($252,338)</td>
<td>($664,906)</td>
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</table>

iii Financial Assumptions

- Initial revenue from sales of outsourced reactor & accelerator products
- Introduction of several internal pharmacy & manufacturing products
- Financed purchase of one manufacturing cyclotron
- Move to internally produced accelerator products
- Financed purchased of additional equipment
- Finance terms 4-5 years, 20% APR
- Two staged CDO projects (one pre-clinical, one phase II/III (MOU in place)
- Conservative market penetration, U.S. only
- No CMO customers
- No international customers

Leadership

Chief Executive Officer: Ph.D. radiochemist & entrepreneur with 30 years in the nuclear industry, both in the Government and Private Sector with over 10 years as a senior operations executive manufacturing FDA approved nuclear medicine products. The CEO has a global presence and maintains strong relationships throughout the industry. He has an extensive background in forming productive strategic partnerships, GMP manufacturing and regulatory processes.

Chief of Pharmacy Operations: 40+ years’ experience in the Nuclear Pharmacy, 23 years as an owner/operator of a small chain of nuclear pharmacies. The CPO has significant experience in nuclear medicine technology, pharmacy operations & logistics.

Chief Medical Officer: M.D. with 20 years in radiopharmaceutical & pharmaceutical development with prior experience directing global medical trials for Bracco Diagnostics, overseeing multiple oncology product clinical trials in the U.S., Europe and Asia for Siemens and directing strategic plans for international multi-center trials for Otsuka Pharmaceuticals. The CMO has a breadth of experience in taking pipeline products through development to late stage trials.

Head of Regulatory Affairs: 20 years senior experience in Quality Management and Compliance most recently with Alcon. Areas of expertise include radiopharmaceutical/API manufacturing, medical devices and general pharmaceuticals. Prior experience with International isotopes in establishing a full radiopharmaceutical quality management program in a start-up facility.
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Head of Facility and Accelerator Engineering: 35 years as a facility and accelerator engineering manager. Formerly at Los Alamos National Laboratory, the Head of FAE was a senior member of the team that established a significant capability for medical isotope production. He has extensive experience in accelerator operations & maintenance and has trained accelerator operators for over 20 years. He has also served as a Radiation Safety Officer in the State of Texas.

The Market for Radiopharmaceuticals

The radiopharmaceutical market is currently undergoing a significant reassessment due to a number of key developments. Data available for 2017 placed the global market size at approximately $5-6B, of which U.S. sales accounted for approximately $1.4B. The dominant sector of the market is diagnostic imaging products with approximately 75-80% of diagnostic sales being attributed to Technetium-99m-based products ($2.6B globally in 2017) used in Single Photon Emission Computer Tomography (SPECT) procedures.

Prior to 2017, most market research predicted that the medium-to-long term growth would be achieved from the introduction and preferred usage of novel Positron Emission Tomography (PET) imaging agents (utilizing established or new agents such as Fluorine-18, e.g. Lantheus/GE Fluoridipaz, Ge-68 from Eckert & Ziegler, etc.) and the increased use of so-called hyphenated techniques (e.g. PET-CT) to achieve improved diagnostic results.

However, the FDA approval of Xofigo, an alpha-emitting therapeutic containing Radium-223 from Bayer and, more recently, of Lutethera, a Lu-177 based ‘theranostic’ from AAA (Novartis), has changed the growth outlook and performance indicators for the nuclear medicine industry (See figure 2). Projections through the mid-2020s that previously uniformly predicted a CAGR of approximately 5% are now as varied as 5-10+% (market size $7.4B – $15.2B in 2024/5). Figure 2 illustrates the reason for this uncertainty showing a predicted ‘hockey-stick’ increase in Global sales associated with the anticipated introduction of new radiotherapeutic agents.

The PET market is still expected to contribute to significant growth within the diagnostic sector, with minor growth from SPECT radiopharmaceuticals coming predominantly as a result of improvements in imaging modalities rather than new products. To successfully compete, The Company will offer APIs in all segments of the radiopharmaceutical market, especially as SPECT isotopes will continue to make up a significant portion of the demand for years to come.

Figure 3 (below) gives a recent (2017) illustration of market drivers and restraints on the growth of the radiopharmaceuticals market, amended to take account of recent developments in applications and the
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overall supply chain. Considering the market driver/restraint assessment shown in figure 3, it can be seen that there is an overall positive growth prediction for the radiopharmaceuticals market, especially when the approval of two ‘new’ classes of radiopharmaceutical for human use, Targeted Alpha Therapy and ‘Theranostics’, are taken into consideration. In addition, an increasing prevalence of chronic diseases indicates the growing need for early diagnosis and treatment is another major factor responsible for the continued growth of the market. Moreover, rising expenditure in oncology and growing emphasis on cancer management has also accelerated the market growth owing to the need for new prompt diagnostic and treatment options for common as well as rare cancers.

In order for continued growth to materialize, a structured approach to product development, approval and availability is needed. The introduction of a new full-service manufacturer and CMO/CDMO is timely and well placed to take advantage of and provide domestic solutions to deficiencies in these areas.

The Company Data Vault, containing a complete diligence package, includes investor information and financial reports on some potential customers and competitors providing valuable information on the radiopharmaceutical market for specific applications. It is worth noting that the ‘hockey-stick’ revenue assessment, seen in Figure 1, is indicative of customers testing the nature and reliability of a product prior to committing to full use and is mirrored in some of the customer/competitor materials.

Competitive Advantage

i. Co-Location of accelerator production and GMP processing for both APIs and ultimately finished pharmaceuticals means less material losses due to radioactive decay. Many products are shipped from the production site to the GMP processor, taking approximately 24 hours and subject to transport delays and cancellations. The loss of material due to decay for short half-life radioactive materials can be significant during this time. The Company will process in the same location as the radioactive materials are manufactured for accelerator produced isotopes.

ii. Risk-adverse strategy whereby the business does not rely on the company obtaining FDA approval for new products but generates revenue from assisting partners develop and commercialize such products.

iii. The close vicinity of a major International airport, which has daily flights from key suppliers abroad, will allow The Company to reach all of the major U.S. markets in less than 6 hours and access export markets for a number of products.

iv. As a manufacturer, the company can offer highly competitive isotope pricing for CDMO clients and negotiate revenue share agreements from the sale and manufacture of final form products

v. The Company’s location has significantly lower overheads than competitors based in geographical areas with higher real-estate and living costs.
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