

cyclomedica technegas ultralute

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# Address to Investors 14 September 2015

# James McBrayer Cyclopharm's CEO, Managing Director & Company Secretary

I would like to present to you what is an exciting and landmark transaction for Cyclopharm. We have released an Announcement to the ASX earlier this morning which contains a summary of the deal.

In short, CYC has signed a term sheet with Jubilant DraxImage ("JDI" or "DraxImage"). DraxImage<sup>1</sup> is a wholly owned subsidiary of Jubilant Life Sciences<sup>2</sup>. Jubilant Life Sciences is a major integrated pharmaceutical company listed on the Indian stock exchange. Jubilant Life Sciences has a strong pipeline of new products supported by facilities in ten countries and over 6,000 employees worldwide. It's an impressive company and a great partner for CYC. Their subsidiary DraxImage is a leader in Nuclear Medicine and has an excellent and highly experienced Regulatory Department which CYC will have access to.

The Term Sheet entered into with JDI outlines the key commercial terms for:

- JDI to fund the development of FDA trials of Technegas;
- a License Agreement for JDI to distribute Technegas in the US; and
- an agreement for JDI to convert the trial funding costs into 15% of CYC's issued share capital, upon successful completion of FDA trials.

We are excited about this transaction and what it means for our shareholders. The US market represents an extremely large, growing and untapped market for Technegas. Consequently this agreement has the potential to deliver significant shareholder value for several important reasons:

- 1. This agreement substantially reduces the risk and financial cost to our shareholders in pursuing USFDA marketing approval,
- 2. JDI has the expertise, resources and capability to accelerate market penetration of Technegas in the USA,
- JDI is highly incentivised to achieve successful USFDA trials. This is because their shareholding in CYC, and of course the ability to market Technegas, will only occur if the trials are a success.

<sup>1</sup> http://www.draximage.com/

<sup>&</sup>lt;sup>2</sup> http://www.jubl.com/



- 4. We believe that a partnership with a party of JDI's calibre will strengthen the practice and use of Nuclear Medicine as an imaging modality in the USA,
- 5. Financially, the economics for the ongoing licensing of Technegas is very strong the License Agreement will generate good returns for shareholders without investing in the substantial capex and opex required in bringing a product to market in the USA, and
- 6. Our strong global Technegas business remains unchanged.

I will now expand on each one of the points:

1. This transaction significantly reduces FDA clinical trial risks to our shareholders. As a result of this agreement, DraxImage will provide USD\$4.5M, at risk, to cover the expected Technegas' Phase 3 clinical trial costs. Should the trial costs exceed USD\$4.5m we will share further costs 50:50 to a commitment by JDI of up to USD\$6m.

With respect to the timing of the trial, we are targeting patient recruitment to be completed by the end of 2016. Following an USFDA regulatory submission and anticipated approval, we expect sales would commence in 2017.

2. We strongly believe, by working with DraxImage, Technegas' penetration in the biggest nuclear medicine market in the world will be accelerated, as opposed to entering into the USA on our own.

As 50% of all nuclear medicine departments in the world are located in the USA, the potential value for CYC shareholders in successfully entering this market is very significant.

In 2014 there was approximately 600,000 nuclear medicine ventilation perfusion studies conducted in the United States to diagnose the presence of pulmonary embolism. We classify 80% or 480,000 studies as the addressable US market for Technegas.

We are highly confident in converting clinical sites to Technegas in the States. We have already accomplished this once in North America. JDI's involvement will enable this process to be accelerated.

By way of reference, Canada is now our largest market in the world. It took us nearly ten years to fully penetrate the addressable market there. In doing so we virtually displaced the other ventilation imaging radiopharmaceuticals. We believe that this partnership will both replicate our success in Canada.

Speed to market was certainly a major driver in our decision; however, particularly important for us in is that DraxImage is the market leader in the US for radiopharmaceuticals used in lung imaging. In fact, they are the sole supplier of DraxImage MAA, in North America, which is the complementary product to Technegas to produce a lung ventilation perfusion image.



Furthermore, DraxImage has the sales and marketing infrastructure and clinical relationships already in place. DraxImage has been vocal about the need for sustainability in nuclear medicine and supporting and underpinning existing and new products.

3. JDI are highly incentivised to make this partnership a success.

In exchange for the trial funding, and only upon FDA approval, DraxImage will be granted new shares in CYC for up to 15% of our issued capital. The shares will be granted in two tranches at market value with no discount. The first tranche will equal 10% of CYC common stock based on Volume Weighted Average Price (VWAP) 30 days prior to making our announcement on 14 September 2014. The value of the remaining 5% will be based on the VWAP 30 days prior to the announcement of attaining USFDA approval.

DraxImage will also nominate a new director to the CYC Board. We will look forward to their contribution backed by specific industry expertise.

This transaction also provides CYC with a shareholder strong industry experience. We will be delighted to see DraxImage as our major industry cornerstone shareholder going forward.

It is important to note that in the event that FDA approval is not achieved DraxImage will be forgoing: their clinical trial cost investment, their rights option for CYC shares and their CYC board position. That being said, we are optimistic of our success together.

4. DraxImage has chosen to partner with CYC so that it can continue to strengthen its position as the market leader in pulmonary imaging and make good on its stated promise of bringing innovative products to the field of nuclear medicine.

Together our collective goal is to promote pulmonary imaging through nuclear medicine. Nuclear medicine is proven to deliver better clinical results in diagnosing pulmonary embolism<sup>3</sup> at a fraction of the radiation burden that CTPA<sup>4</sup> imposes on patients<sup>5</sup>.

In 2014 CTPA in the USA was used to determine the presence of PE in 3.6 million patients<sup>6</sup> ....six times the number of patients diagnosed through nuclear medicine! Together with DraxImage we form a strong alliance to challenge other competing imaging modalities such as CTPA.

In short, this is a powerful partnership.

5. Regarding the commercial outcomes for our shareholders, the license should generate a high level of recurring royalty revenue and profit margin for CYC. It also

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<sup>&</sup>lt;sup>3</sup> European Journal of Nuclear Medicine and Molecular Imaging. 2009 Aug; 36(8):1356-70. DOI 10.1007/s00259-009-1170-5

<sup>&</sup>lt;sup>4</sup> CTPA – Cross tomographic pulmonary angiogram

<sup>&</sup>lt;sup>5</sup> Seminars in Nuclear Med. 2010 Nov;40(6):442-54. DOI: 10.1053/j.semnuclmed.2010.07.007

<sup>&</sup>lt;sup>6</sup> Reference Data – Arlington Medical Resources



removes the need for us to invest in a costly infrastructure in order to sell and support Technegas in the US.

CYC will become a regular royalty receiving -- low cost -- profitable of course --- and highly cash generative company.

Under the license agreement, DraxImage will pay CYC a 17.5% revenue royalty on all Technegas sales generated in the US market. We are very pleased with this result.

DraxImage will also pay CYC a guaranteed 15% margin above our COGS for the supply of Technegas generators and consumables.

The royalty and profit margin will effectively represent pure EBIT in our accounts.

It is my belief that the level of EBIT generated through this royalty agreement will be greater than had we chosen to go it alone into the US.

Needless to say, by partnering with the market leader, our profit will be greater than they would otherwise be and both our risk profile and capital requirements are greatly reduced.

6. Before closing I want to make a few additional points clear.

CYC will continue to sell Technegas through its own established distribution channels outside of the US market as it always has done. We look forward to good sales growth there too.

In no way will this arrangement alter our patent ownership. We will continue to own our patents globally.

Finally, the transaction outlined today is subject to mutual due diligence and is expected to close within 60 to 90 days following the necessary board approvals and signing of a final Licence Agreement.

## **Conclusion:**

We are thrilled with the signing of this term sheet and the start of this partnership. The execution of this Term Sheet demonstrates DraxImage's commitment to invest in and grow the sustainability of diagnostic lung imaging in the US.

For us CYC continues our strategy and passion of bringing innovative globally relevant products that enable physicians to deliver high quality diagnostic outcomes to their patients.



# For more information, please contact:

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### **Background**

#### **Cyclopharm Limited**

Cyclopharm is a radiopharmaceutical company servicing the global medical community. The Company's mission is to provide nuclear medicine and other clinicians with the ability to improve patient care outcomes.

Cyclopharm achieves this objective through the provision of radiopharmaceutical products, Technegas (for lung imaging) and Molecular Imaging (used in cancer, brain and cardiac imaging). Our customers are nuclear medicine departments located within hospitals and clinics.

### **Technegas**

Technegas is a structured ultra-fine dispersion of radioactive labeled carbon. Technegas is produced by drying Technetium-99m, (the most commonly used isotope in nuclear medicine imaging), in a carbon crucible then heating the isotope for a few seconds at around 2,700°C in a Technegas Generator. The resultant gas-like substance is inhaled by the patient (referred to as lung ventilation) via our consumable product known as a Patient Administration Set (PAS).

The inhaled Technegas particles enables multiple views and tomography imaging under a gamma or single photon emission computed tomography (SPECT) camera for the superior functional ventilation imaging primarily used to diagnose pulmonary emboli (blood clots in the lungs).