

Biotech Daily

Friday January 31, 2020

Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Invion

By Tim BOREHAM

ASX Code: IVX

Share price: 1.2 cents

Market cap: \$66.0 million

Shares on issue: 5,500,606,300

Chief executive officer: Craig Newton

Board: Thian Chew (chairman), Mr Newton, Alan Yamahita, Melanie Farris*

Financials (December quarter 2019): receipts \$645,000, cash burn \$447,000, cash on hand \$119,000; all research costs are covered by the Cho Group

Identifiable shareholders: Unlimited Innovation Group (Cho Group) 51.16%, Polar Ventures (Thian Chew) 9.91%, Mr Honsue Cho 5.17%

* Company secretary, Ms Farris replaced Dr James Campbell (who is also CEO of the listed Patrys) in December 2019.

When US Supreme Court judge Louis Brandeis in 1914 opined that sunlight was the best disinfectant, he was referring to the desirability of transparent legal and government processes.

But he could well have been talking about the role of light in shrinking tumors, a treatment that has been known about for a similar amount of time.

Formerly focused on a smoking cessation drug, Invion is emerging as a local exponent of so-called photodynamic therapy.

Invion's solid tumor targets include ovarian cancer, skin cancer and ano-genital cancer, which is as gruesome as it sounds.

Invion created a squeak of excitement in late November when it reported that its Photosoft treatment halved the size of tumors of mice induced with ovarian cancer over three weeks.

The "immediate and specific" death of the tumor tissues was also accompanied by an influx of immune cells, indicating an immune response.

The stock more than doubled after the results of the 48-mouse study, carried out by the Hudson Institute, at Melbourne's Monash University.

After prodding from the ASX, the company admitted the study "was not powered for statistical significance and no statistical analysis was undertaken".

The study, of course, was early stage and rodent studies are notorious for producing encouraging results.

The Hudson Institute is now working over the data ahead of a phase lb trial to treat nonmelanoma skin cancers.

In a separate arrangement, Melbourne's Peter MacCallum Cancer Centre will tackle anogenital cancer. This effort will be overseen by leading cancer research scientist Prof Robert Ramsay, the joint head of Peter Mac's gastrointestinal cancer program.

"We will choose to collaborate with various institutions and hospitals where the expertise fits," says Invion's new CEO Craig Newton.

He notes that 1,500 new cases of ovarian cancer are detected in Australia each year, with 4,000 to 5,000 women already suffering the disease. There are 240,000 patients globally.

"The grim reality is that nearly half of those diagnosed with the cancer will succumb to the disease within five years."

Cho is the go for funding

For a biotech minnow, Invion is in the unusual position of not having to worry too much about fundraising. That's because it is 51-percent owned by the Hong Kong-based Cho Group, which stumps up the dough for all trial work under a research and development agreement.

"This gives us a measure of certainty that doesn't exist with other biotechs," Mr Newton says.

Cho is the corporate vehicle of the Melbourne-based entrepreneur Michael Cho, who was aware of the common use of photodynamic therapy in China.

Ancient history

Formerly known as Cbio, the company listed on the ASX in 2010, raising \$7 million of a hoped-for \$30 million, presumably for an easy exit for its founders, but by August 2011, a 155-patient phase IIa trial showed that XToll (chaperonin 10) failed to meet the primary endpoints for rheumatoid arthritis. It was pretty much all downhill from there.

The company changed its name to Invion in August 2012 and sought to commercialize its anti-inflammatory lead program INV102 (nadolol) as a smoking cessation aid, but could not interest any partners despite looking for two years.

Director and former Chemgenex COO Dr James Campbell brought former Chemgenex CEO Dr Greg Collier into the company in 2013.

In a back-door listing deal in late 2017, the company entered an exclusive distribution and licence agreement to commercialize and develop Cho's Photosoft. The deal involved Cho Group subscribing for \$5.5 million of shares at 0.2 cents each and Cho underwriting a \$2.5 million rights issue at the same price.

In a 2019 deal, the Hudson Institute said it would partner with Invion to research and develop the next-generation photodynamic therapy.

Hudson will provide research and clinical expertise, while Cho Group will continue to stump up the spendoolies.

In October last year, the company and Peter Mac announced a collaboration to research ano-genital cancers.

The trouble with penile and anal cancers is that sufferers are too embarrassed to see their doctor until it's too late.

The company's CEO for six and a half years, Dr Greg Collier retired on October 31 last year and was replaced by Mr Newton, the company's chief operating officer since April 2018.

(Dr Collier founded Chemgenex, which won regulatory approval for its chronic myeloid leukaemia drug before being taken over by Cephalon for \$230 million in 2011).

In September 2018, Invion said it would package up its respiratory assets - nadolol and a respiratory treatment called zafirlukast - and spin them off as a separate unlisted entity focused on the China market.

In February last year, Chronic Airways Therapies was born, with Invion holders receiving shares on a one-for-one basis as part of the in-specie distribution. Invion also undertook a 0.3 cents a share capital return.

"Fundamentally the trajectory remains the same," Mr Newton says. "The company's efforts are built around building Photosoft technology as a basis for ... getting through relevant regulatory scrutiny."

Seeing the light

Light therapy dates back to 1903, when Faroe Islander and Danish physiologist Prof Niels Finsen snagged a Nobel Prize for his work in the area.

At least 500 trials have been carried out since.

"Light therapy has been around for a long time but for various reasons it hasn't taken off," Mr Newton says.

He notes the so-called first-generation light treatments were problematic in a few ways: they were derived from toxic materials and it took two to three months for the body to clear them. They also had limited membrane penetration and thus efficacy.

Photosoft uses non-toxic photo-sensitizers that react with visible light and oxygen to kill malignant cells in a chain reaction.

Photodynamic therapies are thought to kill malignant cells, shut down tumors and stimulate the immune system.

Photosoft uses a laser light activation method based on short, pulsating 'near infrared' wavelengths.

Photosoft is chlorophyll (plant) based and only accumulates in the actual cancer cells.

It produces singlet oxygen, a cytotoxic reactive agent that allows more effective zapping of the bad cells.

In the late 1970s, the New Jersey-based Roswell Park Cancer Institute developed photodynamic therapies. In the 1990s, they were used for prostate cancer. In 1995, the US Food and Drug Administration agreed the truth indeed was out there and approved the use of the therapy for oesophageal cancer.

In 2017, Israeli biotech Steba Biotech won European approval for its light therapy prostate cancer treatment, Tookad.

With skin cancer, the company is targeting basal cell carcinomas and squamous cell carcinomas, the non-melanoma ones that are not generally life threatening.

The current standard-of-care involves cutting or freezing them off.

"Cosmetically, the results are poor," Mr Newton says. "This market represents low hanging fruit for a topical formulation."

Mr Newton says the therapy potentially could also be used as an adjunct to surgery or chemotherapy.

Other tumors of interest are lung cancers, including mesothelioma.

Financials and performance

As we noted previously, Invion is pre-revenue and externally funded so the company's financials are more of a case of 'nothing to see here, move on'.

For the record, Invion burnt \$447,000 of cash in the December quarter and ended 2019 with cash of \$119,000. The burn rate was affected by the timing of invoices, as pre-agreed between the parties.

In the last year Invion shares have traded between 0.8 cents (ahead of the November 26 trial results) and 2.6 cents (April 11). Historically the stock has traded as high as 4.8 cents (April 4, 2018).

Dr Boreham's diagnosis:

As the only ASX-listed biotech in the photodynamic therapy game, Invion at least has a rarity value. Management has done well to snare the Cho and Hudson deals, but it is very much a work in progress.

The unanswered question is whether Photosoft has clear clinical advantages and much more work needs to be done. In the short term, investors can expect some skin cancer results this year.

"Things are moving quite quickly," Mr Newton says. "We are pretty confident when we look at the penetration of the drug, we have something broadly applicable."

Overall, he says, the key to development is to bring years of experience in photodynamic therapy development into a modern regulatory framework.

"It is essentially an established concept but the key has been to make it clinically relevant," he says. "We are putting the support we have to good use."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He was sceptical about photodynamic therapy but has now seen the light.