



Together, we turn possibilities into realities  
**Your trusted softgel CDMO partner**



# Douglas is your trusted softgel CDMO partner that develops medicines to improve lives



Douglas CDMO is a division of Douglas Healthcare, an established pharmaceutical company with a world class reputation for high standards in product development and manufacturing.

**We have an impressive track record in developing and supplying pharmaceutical softgel products to the US and EU markets, and we export to over 40 countries around the world.**

Our base in Auckland, New Zealand enables us to deliver a unique combination of value for money, highly personalized and IP secure CDMO solutions. We leverage our international experience, development expertise and fit for purpose equipment, to deliver to your unique project needs.

We partner with pharmaceutical and biotechnology companies in the US to deliver tailored formulations and support the launch of market leading products.

Our team of development, regulatory, manufacturing and program management experts thrive on crafting solutions that fit your project's exact requirements. We stand ready to support you in navigating complex regulatory pathways, ensuring that your project progresses seamlessly from concept to market.



## **A trusted partner**

We deeply understand the magnitude of a decision to outsource your development program. We have a track record of building longstanding and highly collaborative relationships – our partnerships exemplify innovation, tenacity and a mindset towards delivering long-term value. We do what we say we will through every stage of the project journey to achieve successful outcomes for our partners. We recognize that confidentiality and speed to market are core to your commercial success.



## **Quality at the center**

Quality has been intrinsic to our success over many decades and is central to the way we work. Our quality management system complies with cGMP requirements and we are audited by the US FDA, Health Canada and other international health authorities. We have mutual recognition on GMP with the UK and the EU. We embed quality-by-design principles from the early stages of development right through to the launch of your product.



## **High potency capability**

We have over 30 years' experience in handling high potency small molecules with successful registration of retinoid, hormone and cytotoxic products. This capability, in combination with our specialization in softgel technologies, offers you the ability to develop and manufacture your compounds safely.



## **Softgel**

Many small molecule candidates in development are poorly soluble and/or poorly permeable compounds. The softgel platform offers you a way to optimize oral bioavailability of these compounds and to stabilize those that are unstable to oxygen and moisture.



## **Value for your investment**

We offer a competitive solution, leveraging our high staff retention rate and location to your IP advantage. The path to human clinical studies is also efficient and phase 1 clinical studies can be conducted in New Zealand without opening an IND. Our highly experienced and well educated workforce operates within state-of-the-art facilities and successfully utilizes time zone differences with US and EU partners. In combination with our organizational values and culture, we provide a compelling value proposition that will impress you.

# Douglas US and EU Softgels

Through collaborative relationships we have successfully developed multiple softgel products, and the majority of those launched continue to be supplied by Douglas to our in-market partners

## Softgels developed by Douglas

### Endocrinology

#### Paricalcitol Softgel Capsules

Generic of AbbVie's Zemplar®

2015

In-Market ✓

#### Calcitriol Softgel Capsules

Generic of Roche's Rocaltrol®

1999

In-Market ✗

### Dermatology

#### Isotretinoin Softgel Capsules

First in world generic of Roche's Roaccutane®

2001 (EU) 2010 (USA)

In-Market ✓

#### Alitretinoin Softgel Capsules

First in the world generic of GSK's Toctino®

2018

In-Market ✓

#### Isotretinoin Low Food Effect Softgel Capsule

Generic of Sun's Absorica®

2021

In-Market ✓

### Men's and Women's Health

#### Dutasteride Softgel Capsule

Generic of GSK's Avodart®

2015

In-Market ✗

#### Norethindrone Acetate and Ethinyl Estradiol Softgel Capsule

Generic of AbbVie's Taytulla®

2022

In-Market ✗

#### Vaginal pessary

NDA investigational medicinal candidate to treat high grade cervical dysplasia

In Phase 2

In Development

### Oncology

#### Bexarotene Capsules

Generic of Valeant's Targretin®

2018

In-Market ✓

#### Tretinoin Capsules

Generic of Roche's Vesanoid® and now only supplier for the US market

2016

In-Market ✓

#### Retinoid softgel

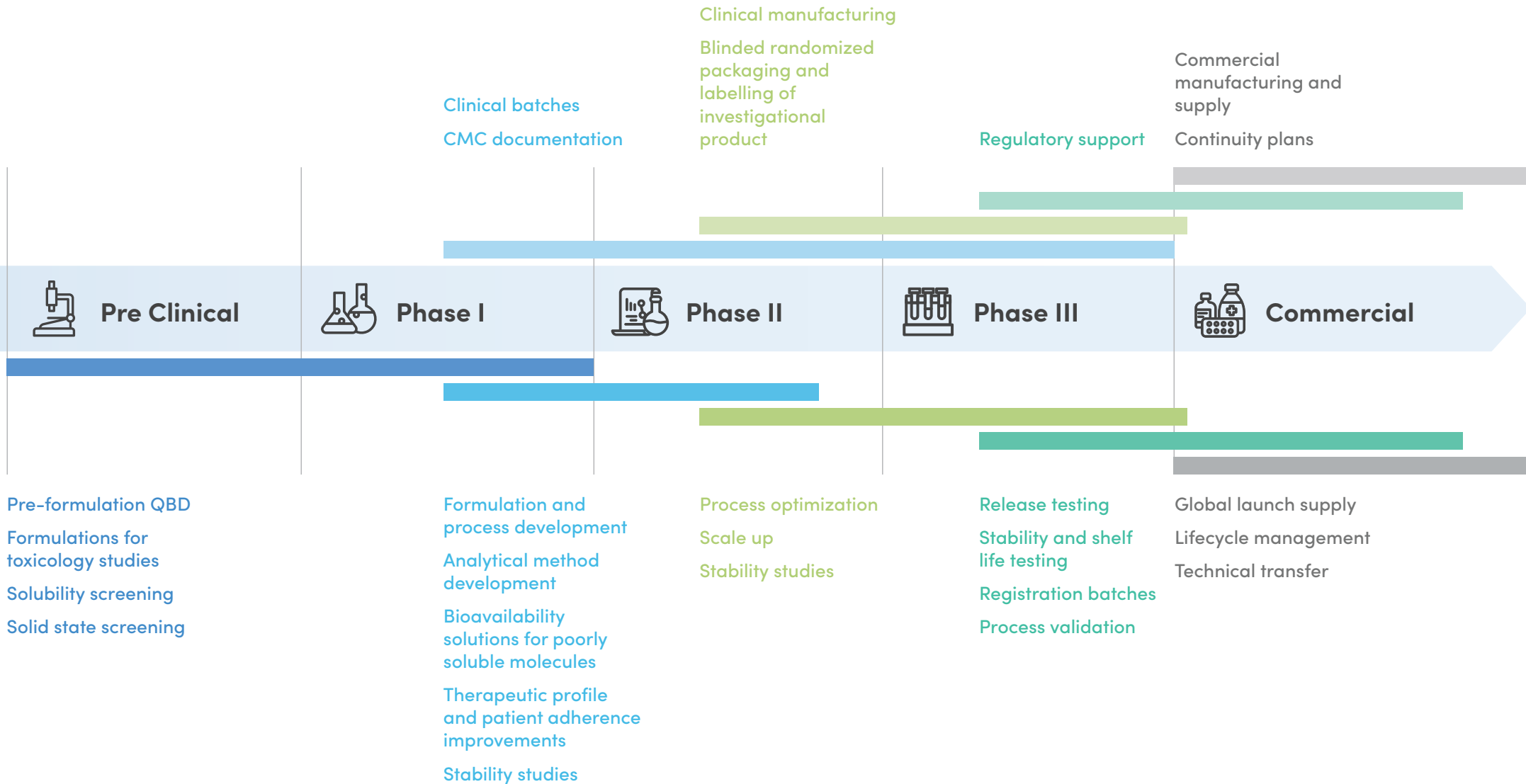
NDA investigational medicinal candidate as an adjunctive treatment of solid tumors

In Phase 2

In Development

# Your Product Pipeline Journey

High potency, hormones and cytotoxic softgels





A person wearing a white lab coat and blue gloves is operating a piece of industrial machinery. The person's hand is on a control panel that features a touchscreen display and several physical buttons. The machinery is complex, with various pipes, hoses, and a large stainless steel vessel. The background shows a clean, industrial setting with a blue-tinted overlay.

Let us **partner**  
**with you on your**  
**next project**

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