



## Company Overview

**Unigene Laboratories** (OTCBB: **UGNE**) is a biopharmaceutical company focusing on the oral and nasal delivery of large-market peptide drugs. Due to the size of the worldwide osteoporosis market, Unigene is targeting its initial efforts on developing calcitonin and parathyroid hormone-based therapies. The Company's first U.S. Product, Fortical<sup>®</sup>, was approved and launched in August 2005. Unigene's patented oral delivery technology has successfully delivered, in preclinical and/or clinical trials, various peptides including calcitonin, parathyroid hormone and insulin. Unigene's patented manufacturing technology is designed to cost-effectively produce peptides in quantities sufficient to support their worldwide commercialization as oral or nasal therapeutics. Pharmaceutical partners include GlaxoSmithKline, Upsher-Smith Laboratories and Novartis. Unigene has also developed Site-Directed Bone Growth technology which may be able to repair damaged bone, potentially representing a minimally invasive procedure to prevent and treat hip and vertebral compression fractures.

## Key Statistics

(as of March 2010)

<b>Symbol</b> .....	UGNE
<b>Market</b> .....	OTC:BB
<b>52 wk High</b> .....	\$1.96
<b>52 wk Low</b> .....	\$0.37
<b>Shares Outstanding</b> .....	91.41M
<b>Float</b> .....	73.04M
<b>Market Cap</b> .....	\$55.76M
<b>Avg. Daily Volume</b> .....	104,126
<b>Price</b> .....	\$0.61

## Management

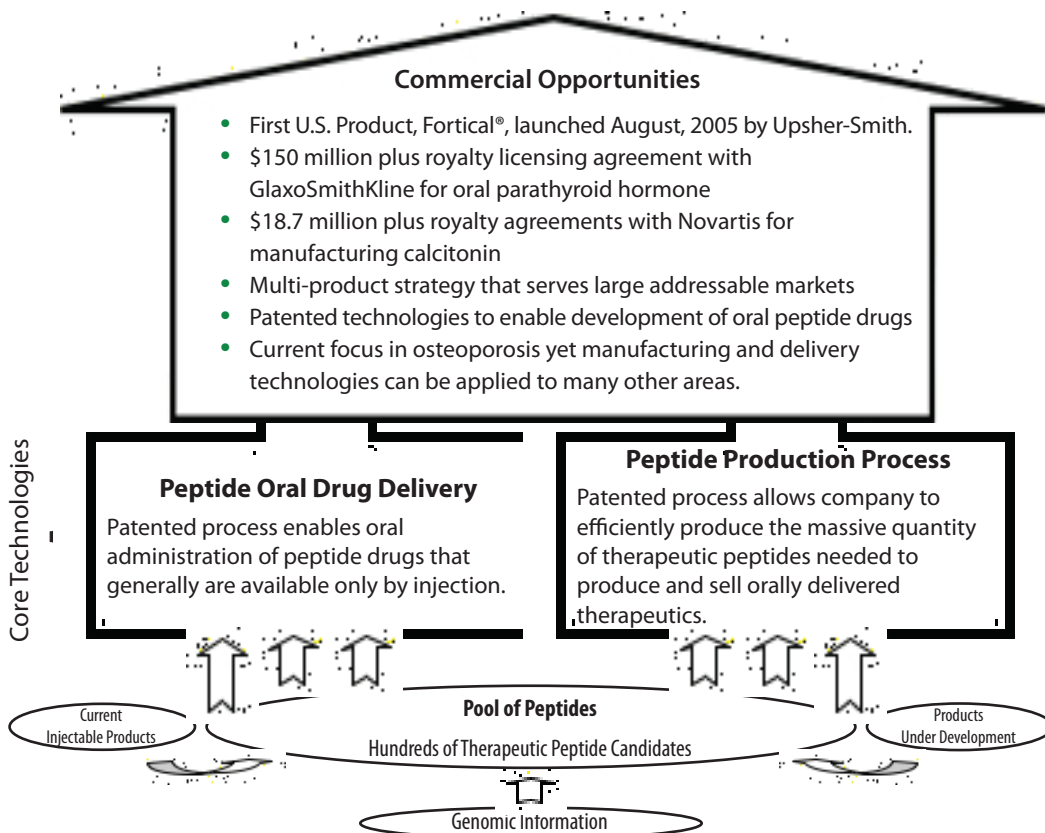
**Warren Levy, Ph.D.**  
President and CEO

**Ronald Levy, Ph.D.**  
Executive Vice President and Secretary

**William Steinhauer**  
Vice President of Finance

**James Gilligan, Ph.D.**  
Vice President for Product Development

## Investment Highlights



## Investor Relations

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## Oral Drug Delivery

Oral delivery of medication is the method of administration generally preferred by most patients and its convenience leads to improved patient compliance. In order to deliver peptide drugs orally one must prevent the premature destruction of the drug by stomach acids and enzymes, as well as facilitate transport of the drug through the intestine into the bloodstream. Unigene's patented oral delivery technology successfully overcomes these obstacles. A worldwide exclusive license was granted to GlaxoSmithKline (GSK) for oral delivery of parathyroid hormone (PTH).

# Peptide Production Process

Peptide drugs delivered by non-injectable methods of administration inherently require significantly higher levels of the drug per dose in order to deliver equivalent levels of peptide into the bloodstream. An abundant source of relatively inexpensive peptide is generally required in order to enable the development of a commercially successful product. Unigene's patented recombinant production technology is capable of producing extremely large quantities of highly-purified peptide while dramatically reducing production costs, and may uniquely enable the commercialization of certain peptide drugs in oral form. The technology has been licensed to GSK for PTH and to Novartis (NVS) for calcitonin. NVS has used the technology to produce calcitonin for an oral formulation that is currently in Phase III clinical trials for osteoporosis and osteoarthritis.

## Product Pipeline

### Calcitonin

Calcitonin products have been marketed for more than 30 years to treat postmenopausal osteoporosis with a very favorable safety profile and no major contraindications. Calcitonin is a naturally occurring hormone that also exhibits analgesic properties.

#### Fortical® - nasal calcitonin product (Osteoporosis)

- Received U.S. FDA approval and launched product in August 2005.
- Licensed U.S. rights to Upsher-Smith Laboratories (USL).
- Fortical currently holds over 50% of the ~\$200 million US calcitonin market.
- Product differentiated by economical pricing model, active promotion, robust early-stage clinical data, different preservative and different formulation.
- Patented formulation.
- NDA filed in China for injectable and nasal calcitonin in September 2003.

#### Oral Calcitonin Products - Novartis (Osteoporosis and Osteoarthritis)

- Unigene licensed worldwide calcitonin manufacturing rights to NVS for \$18.7 million plus royalties.
- Unigene receives up-front and milestone payments in addition to royalties upon commercialization of any NVS product containing calcitonin made by Unigene's process.
- Unigene can purchase calcitonin manufactured by NVS at a significantly larger scale, to support increased demand for current and future calcitonin products, without spending the estimated >\$50 million in capital to construct larger facilities.
- Novartis has used the process to produce calcitonin for an oral formulation, currently in Phase III testing for osteoporosis and osteoarthritis.

#### Oral Calcitonin Products – Unigene (Osteoporosis, Osteoarthritis and Other Inflammatory Diseases)

- Two formulations being developed – calcitonin alone and in combination with glucocorticoids. The combination product may potentially be used to treat osteoporosis, and inflammatory diseases including osteoarthritis, inflammatory bowel disease and asthma.
- Phase I/II clinical studies demonstrated delivery of calcitonin into the bloodstream.
- Worldwide sales potential for oral calcitonin products could exceed \$1 billion.

#### Oral Parathyroid Hormone (Osteoporosis)

- Unigene licensed exclusive worldwide rights for manufacturing and oral delivery to GSK for \$150 million plus royalties.
- Worldwide market potential could exceed \$1 billion.
- PTH is a naturally occurring hormone. An injectable PTH analog sold by a third party is the only currently approved U.S. product for osteoporosis that primarily works by a unique bone-building model. That product has annual sales in excess of \$750 million.
- Other treatments for osteoporosis that slow the rate of bone loss may be investigated in the future in combination with PTH.
- GSK has completed initial Phase I studies showing therapeutic blood levels of the intact, active peptide. Unigene is currently developing improved formulations of oral PTH for further clinical study.

#### Site-Directed Bone Growth (Treatment/Prevention of Hip and Vertebral Compression Fractures, Treatment of Long Bone Fractures)

- Technology invented in collaboration with Yale University Medical School, and being developed in collaboration with investigators at Yale and Johns Hopkins Medical School.
- Pre-clinical studies demonstrate significant natural bone growth only at targeted location that can be formed and maintained using existing biological products.
- Minimally-invasive procedure should not require long or expensive hospitalization or non-natural materials.
- Worldwide sales potential could exceed \$1 billion for each application.

Product Pipeline	Preclinical	Phase I/II	Phase III	Approved/Marketed	Current or Projected Market	Indications
Nasal calcitonin (US)					~\$200 million	Osteoporosis
Oral calcitonin (Novartis)			→		>\$1 billion	Osteoporosis, Osteoarthritis
Oral calcitonin (Unigene)			→		>\$200 million	Osteoporosis
Oral calcitonin/ glucocorticoid (Unigene)	→				>\$1 billion	Osteoporosis, Osteoarthritis and Inflammatory Diseases
Oral PTH		→			>\$1 billion	Osteoporosis
Site-Directed Bone Growth	→				>\$1 billion per indication	Treatment/Prevention of Vertebral Compression and Hip Fractures, Treatment of Long Bone Fractures

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