Rapid, Reliable Pain Relief

Rapid-acting pain medications based on the patented FFT Medical Oral Transmucosal Film (OTF)
Dr. Scott Boyer

- Trained as Toxicologist – Univ. Colorado, Boulder & Karolinska
- In the first wave of ’Young Talent’ recruited to Pfizer 1993
- Moved to Astra Hässle, Mölndal 1997
- Helped design new Global Structure of AstraZeneca 1999
- Chief Scientist 2008
1

ATTRITION IN DRUG DISCOVERY AND DEVELOPMENT

SCOTT BOYER¹, CLIVE BREALY² AND ANDREW M. DAVIS²
¹Swedish Toxicology Sciences Research Center, Södertälje, Sweden
²AstraZeneca R&D, Möln达尔, Sweden

1.1 “THE GRAPH”

If we had a confident grasp of the underlying reasons for attrition of projects and compounds in drug discovery and development, we would not need to write this book. But we are not confident, not confident at all. The molecules, and they share so many symptoms, are crippling the industry.

Vision

Improved quality of life for people who experience severe pain
Business Concept

Develop treatment methods with unique properties in the therapeutic fields of migraine and pain related to cancer.
Concept behind Klaria started in 2012

Rapid-acting pain relief products designed for growing markets where current products are sub-optimal and/or expensive to manufacture

Exclusive, worldwide, fee-free and permanent license for film technology
Transmucosal Film Technology

- Alginate polymer extracted from North Sea brown algae
- Approved for food and drug use worldwide
- Patented
# FFT OTF Film Patent

P723400 Patent family

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>2006327277</td>
<td>Granted</td>
<td>2006327277</td>
<td>2013-03-25</td>
<td>2026-12-22</td>
</tr>
<tr>
<td>Brazil</td>
<td>PI0620403-1</td>
<td>Pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Canada</td>
<td>2633878</td>
<td>Granted</td>
<td>2633878</td>
<td>2015-02-10</td>
<td>2026-12-22</td>
</tr>
<tr>
<td>China</td>
<td>200680048866.3</td>
<td>Granted</td>
<td>ZL200680048866.3</td>
<td>2013-03-27</td>
<td>2026-12-22</td>
</tr>
<tr>
<td>EPC</td>
<td>06844046.0</td>
<td>Pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hong Kong</td>
<td>09101443.2</td>
<td>Pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCT</td>
<td>PCT/SE2006/050626</td>
<td>In national phase</td>
<td>n.a.</td>
<td>n.a.</td>
<td></td>
</tr>
<tr>
<td>India</td>
<td>5142/DELNP/2008</td>
<td>Pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Israel</td>
<td>191994</td>
<td>Granted</td>
<td>191994</td>
<td>2013-12-31</td>
<td>2026-12-22</td>
</tr>
<tr>
<td>Japan</td>
<td>2008-547188</td>
<td>Granted</td>
<td>5425471</td>
<td>2013-12-06</td>
<td>2026-12-22</td>
</tr>
<tr>
<td>Mexico</td>
<td>MX/a/2008/007839</td>
<td>Granted</td>
<td>331293</td>
<td>2015-07-03</td>
<td>2026-12-22</td>
</tr>
<tr>
<td>New Zealand</td>
<td>569261</td>
<td>Granted</td>
<td>569261</td>
<td>2012-12-11</td>
<td>2026-12-22</td>
</tr>
<tr>
<td>Norway</td>
<td>20083226</td>
<td>Pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Russia</td>
<td>2008130391</td>
<td>Granted</td>
<td>2445977</td>
<td>2012-03-27</td>
<td>2026-12-22</td>
</tr>
<tr>
<td>South Africa</td>
<td>2008/05287</td>
<td>Granted</td>
<td>2008/05287</td>
<td>2009-11-25</td>
<td>2026-12-22</td>
</tr>
<tr>
<td>South Korea</td>
<td>10-2008-7018096</td>
<td>Pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>South Korea</td>
<td>10-2014-7008366</td>
<td>Granted</td>
<td>10-1484530</td>
<td>2015-01-14</td>
<td>2026-12-22</td>
</tr>
<tr>
<td>Sweden</td>
<td>0502900-4</td>
<td>Granted</td>
<td>0502900-4</td>
<td>2008-03-18</td>
<td>2025-12-23</td>
</tr>
<tr>
<td>USA</td>
<td>12/158472</td>
<td>Granted</td>
<td>8759282</td>
<td>2014-06-24</td>
<td>2029-04-17</td>
</tr>
</tbody>
</table>
Leadership

Board of Directors

Erik Nerpin
Chair

Scott Boyer
Member, CEO

Thomas Ohlin
Member

Operational Leadership Team

Susan Suchdev
Chief Operations Officer

Leif Ingemarsson
Chief Technical Officer

Hans Richter
Chief Financial Officer
Leadership: Scientific Advisory Board

Dr. Robert Holland: Developer of Zomig and many other megabrands

Prof. Robert Glen: Co-Inventor of Zolmitriptan

Dr. Karsten Ahlbeck: Dept. Head Pain Clinic, St. Görans, Stockholm
Focus Areas
Klaria: Focused where rapid relief counts

3.7 Billion/yr
Migraine

3.5 Billion/yr
Breakthrough Cancer Pain
Migraine

- Neurological disease
- Recurrent moderate to severe headaches
- Pulsating in nature
- Lasts from 2 to 72 hours.
- Nausea, vomiting, and sensitivity to light, sound, or smell
The Impact of Migraine

Over 37 million people in the US live with migraines.

...resulting in an ER visit every 10 seconds for migraine or headache...

...impacting one in four US households.

90% are unable to work or function normally during a migraine attack.

6.2 times greater risk of suicide...

$31 billion in direct and indirect annual economic costs.

Source: www.migraine.com
Call to Action

Migraine Underdiagnosed

Diagnosed Patients Require Better Management

Headaches
Diagnosis and management of headaches in young people and adults

Clinical Guideline 150
Methods, evidence and recommendations
September 2012

Commissioned by the National Institute for Health and Clinical Excellence
Medical Need: Rapid Onset of Action

Migraine Pain

Time

Tablet
Klaria’s Products: Rapid Onset of Action

Migraine Pain

Time

Klaria Film

Tablet
Placed Where Others Want to Be

- Fast Onset: Inhalation, Nasal Sprays, Transdermal
- Slow Onset: Tablets, Oral Liquids
- Difficult to use: Injectables
- Easy to use: Klaria Films

Klaria Films

Injectables
Nasal Sprays
Transdermal
Inhalation
Oral Liquids
Tablets
The seven available triptans (plus one combination pill) differ in their effectiveness and the side effects they cause. They are fairly expensive (three—naratriptan, rizatriptan, and sumatriptan—are now available as generics), ranging from $12 to $46 per pill. The nasal spray and injectable forms cost more.

Consumer Reports – USA, 2013
Prescription Migraine Market

- Treatment
  - Triptans
  - Ergots

Source: Global Migraine Markets 2015-2019, TechNavio
The Big Three

First line Migraine therapy and >80% of triptan market – all now generic

- Sumatriptan
- Zolmitriptan
- Rizatriptan
When Triptans do not work

DHE* – 2nd Line Therapy

*DHE = dihydro-ergotamine, commonly called ‘ergot’
Klargia: Focused where rapid relief counts

3.7 Billion/yr
Migraine

3.5 Billion/yr
Breakthrough Cancer Pain
Breakthrough Cancer Pain

BCP Control

Normal Pain Control
Breakthrough Cancer Pain

- Patients with cancer-related pain not controlled by their current therapy
- Can be already on continuous opiate analgesics
- BCP medications used to control acute bouts of pain
Breakthrough Cancer Pain

Market Development

- $3.7 Billion market in 2018.

- BCP will be the fastest-growing market in pain – growing at about 15% per year.
Analgesia Products to Beat

Fentanyl
- Actiq®
- Fentora Buccal®
- Abstral®

Oxycodone
- Oxynorm®

Sublingual or Buccal
Oral Liquid
Competitor Pricing – A Weakness
Who is the Customer?
# Klaria’s High Value Pipeline – All Generics

<table>
<thead>
<tr>
<th>Area</th>
<th>Migraine</th>
<th>BCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pipeline</td>
<td>Triptans (3)</td>
<td>Analgesics (2)</td>
</tr>
<tr>
<td></td>
<td>DHE (1)</td>
<td></td>
</tr>
<tr>
<td>Comparison Value*</td>
<td>$144M (2014)</td>
<td>$90M/17%Sales (2012)</td>
</tr>
<tr>
<td></td>
<td>$958M (2013)</td>
<td></td>
</tr>
</tbody>
</table>

*most relevant recent public drug delivery license agreements
Development Timelines
Milestones to Launch | Triptans, DHE, Analgesics

Formulation Development
Testing of optimal conditions for absorption

Initial human trials
Uptake rate and dose-finding trials in humans

Formal Bioequivalence Studies

Regulatory Interactions
Discussion with Regulatory authorities on development plans

Regulatory Program 505(b)(2)
Assembly of materials for regulatory submission

CMC product development to launch

Submission

Launch

Time:

2016

Cost/product 0.3-0.4M€

2017

Cost/product 0.6M€

2018

Cost XM€
Klaria as an Investment

- 6 Projects
- Deal Value per project $50+ Million
- Relatively Low Risk