Transforming the Battle Against Cancer
Disclaimer

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Our Mission

NanOlogy™ has transformed systemic chemotherapy into LOCAL DELIVERY to improve the lives of patients with cancer and other serious illnesses.
Systemic Paclitaxel and Docetaxel: Effective but Limited

Among the World’s Most Prescribed Cancer Agents

- Breast Cancer
- Bladder Cancer
- Lung Cancer
- Squamous Cell Cancer
- Ovarian Cancer
- Prostate Cancer
- Pancreatic Cancer
- Pancreatic Cysts
- Head & Neck Cancer
- Cutaneous Metastases

IV dose and frequency of dose are limited by systemic toxicity
“Researchers have known for decades that paclitaxel and docetaxel are effective cancer killing agents, and have long searched for ways to retain high concentration of drug at the treatment site to increase efficacy and safety.”

— Maurie Markman, MD, President of Medicine and Science, Cancer Treatment Centers of America®

- Paclitaxel
- Cremophor® EL co-solvent
- IV infusion over 1 hour
- Pretreatment with antihistamine/steroids
- Systemic dose limited by paclitaxel and Cremophor toxicity

- Paclitaxel
- Albumin bound
- IV infusion over 30 minutes
- No pretreatment
- Systemic dose limited by paclitaxel toxicity

- Paclitaxel
- Naked (uncoated) submicron particles of pure drug
- Suspended in saline diluent
- Local Delivery
Local Delivery of Particles versus Solution

- Paclitaxel and co-solvent in **solution**
- If injected into tumor, drug would leak out by simple diffusion
- Rapidly cleared systemically over one to two days

- Suspended **submicron particles of pure drug**
- Entrapped in tumor releasing drug at therapeutic levels over several weeks
- Gradual clearance at low levels over several weeks
NanOlogy™ Submicron Particle Production Technology

API Crystals: **Too Big**
- Cannot suspend or inject
- Insufficient drug release

Single API Molecule: **Too Small**
- Short half life with rapid clearance from body

NanOlogy Technology
- Supercritical Fluid CO₂
- Sonic Energy

Submicron Particles: **Right Size**
- Can be suspended, locally delivered
- Particles entrapped at disease site increasing residence time
- Increased particle surface area allows for sustained therapeutic API release

0.6 microns

20-100 microns
Paclitaxel and Docetaxel Submicron Particle Platform

Strong Value Proposition

Proven Drugs
Local Delivery

Concentrated Dose
Longer Residence Time
Less Systemic Exposure

- Six Phase 2 Clinical Trials Underway
- Clinical Results in 2018
- Preclinical Data in Lung, Breast, Bladder and Other Cancers
- Potentially Synergistic with Other Therapies
- Extensive Intellectual Property Portfolio including composition patent
- Streamlined 505(b)2 Regulatory Pathway
Four Unique Products

- NanoPac® Sterile Suspension
- NanoDoce® Sterile Suspension
- NanoPac® Topical

Intraperitoneal  Intratumoral
Intracystic      Intracompartmental
<table>
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<th>Product</th>
<th>Delivery</th>
<th>Sponsor</th>
<th>Indication</th>
<th>Preclinical</th>
<th>Phase 1</th>
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<th>Phase 2ab</th>
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<td>Sterile Nanoparticle Docetaxel</td>
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Concentrated Local Delivery

**NanoPac®**
Preclinical Tumor Reduction (Prostate)

- **Group 1:** Vehicle, IT, 3 doses
- **Group 2:** Paclitaxel 30 mg/kg, IV, 3 doses
- **Group 3:** NanoPac 12.5 mg/kg, IT, 3 doses
- **Group 4:** NanoPac 37.5 mg/kg, IT, 3 doses

**NanoDoce®**
Preclinical Tumor Reduction (Bladder)

- **Group 1:** Vehicle, IT, 3 doses
- **Group 2:** Docetaxel 30 mg/kg, IV, 3 doses
- **Group 3:** NanoDoce 100 mg/kg, IT, 2 doses
- **Group 4:** NanoDoce 100 mg/kg, IT, 3 doses
Long Residence Time at Disease Site

**NanoPac® Preclinical Residence Time**
- Prostate (intratumoral): > 28 days
- Peritoneum (instillation): > 28 days
- Breast (intratumoral): > 28 days
- Lung (inhalation): > 14 days

**NanoDoce® Preclinical Residence Time**
- Prostate (intratumoral): > 28 days
- Breast (intratumoral): > 28 days

**Phase 1 Ovarian Cancer Study**
- Peritoneal concentrations were 450-2900 times greater than peak plasma drug concentrations
- Low systemic clearance levels
- 5 of 21 salvage patients survived beyond 400 days

Preclinical data on NanoPac® via nebulized inhalation for lung cancer:

- PK studies show drug retained in lung tissue greater than 14 days with no gross or histologic abnormalities in lung tissue
- Pharmacology study completed December 2017
Preclinical Safety Data

Preclinical Inhalation Studies
- No lung abnormalities
- No histological changes
- No drug-related adverse events

Preclinical 28-Day Dermal Toxicity Study
- No dermal irritation compared to vehicle
- Minimal systemic absorption

Preclinical Tissue Injection Toxicity Study
- Well tolerated to maximum feasible dose with minimal local tissue effects

Preclinical Repeat Dose Intraperitoneal Study
- Gradual clearance from the peritoneum
- “Depot effect” with measurable plasma paclitaxel levels 45-119 days after dosing

Preclinical Inhalation Studies
- No lung abnormalities
- No histological changes
- No drug-related adverse events
Clinical Safety Data

Phase 1 Clinical Trial in Peritoneal Malignancies
• Reduced toxicity compared to GOG studies
• No drug-related bowel obstruction
• Low peritoneal clearance

Phase 2 Clinical Trials
• No drug-related serious adverse events

Phase 1 Clinical Trial (12 patients)
• No dermal irritation
• Negligible systemic absorption

Phase 2 AK Clinical Trial (3 of 4 cohorts)
• Minimal irritation or local skin reactions
• Negligible systemic absorption
Potential Synergy with other Cancer Therapies

Taxanes increase the effectiveness of other therapies

- Growing body of evidence for combining taxanes with other forms of cancer therapy to increase efficacy
- Numerous clinical trials underway using taxanes in combination with other therapies

Systemic taxanes have limitations

- Dose and frequency of dose are limited by systemic toxicity
- Systemic toxicity is additive to the toxicity of other therapies

NanOlogy™ products do not share these limitations

- Locally delivered in high concentration
- Do not depend on systemic circulation to reach the tumor
- Systemic side effects are minimal because of gradual drug clearance at low levels

Taxanes increase the effectiveness of other therapies

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Expanding Intellectual Property Portfolio

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<th>Category</th>
<th>Details</th>
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<tr>
<td><strong>Composition</strong></td>
<td>- US 9,814,685 - Expires Jun 2036 - 12 ROW patents pending</td>
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<tr>
<td><strong>Process</strong></td>
<td>- 48 issued or pending patents</td>
</tr>
<tr>
<td><strong>Formulation</strong></td>
<td>- 2 pending patents</td>
</tr>
<tr>
<td><strong>Use/Indications</strong></td>
<td>- 23 issued or pending patents</td>
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<tr>
<td><strong>Therapeutic Combinations</strong></td>
<td>- 1 pending patents</td>
</tr>
<tr>
<td><strong>Orphan Drug Designation</strong></td>
<td>- 1 granted and others pending</td>
</tr>
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</table>

- Paclitaxel and Docetaxel nanoparticles
- Particle size
- Density
- Specific surface area
- Dissolution
- Forms proposed product specifications

NME-like advantages
Annual US Drug Treatment Costs

- Lung Cancer: $4.5B
- Prostate Cancer: $3.3B
- Actinic Keratosis: $2.0B
- Pancreatic Cysts: $1.1B
- Cutaneous Metastases: $0.9B
- Pancreatic Cancer: $0.7B
- Ovarian Cancer: $0.5B
- Bladder Cancer: $0.3B

Total: $13.3 Billion
• Founded NanOlogy™
• Private Texas company formed in 1990
• Successful track record of pharmaceutical startups, product development, L&A, and operations
• $1.5 billion in value realized
• NanOlogy funding and overall management

Unique collaboration through complimentary capabilities
Lead by an Experienced Team

Management

H. Paul Dorman, CEO (DFB)
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Mark Mitchell, Legal (DFB)
Max Lea, Corporate Development/Finance (DFB)
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Actinic Keratosis
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Seeking partners to advance development through pivotal trials, regulatory approval, and to market
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