New York University

Collaborations with Industry, Conflict of Interest, Data Sharing and Ownership

May 24, 2011

New York University

Technology Transfer at NYU

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Mission Statement

Promote the commercial development of NYU technologies into products to benefit patients and society, while providing a return to the University to support its research and education missions.

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Activities

- Commercialization of NYU Technologies
- Research Support from Industry
- New Business Ventures
- Biological Material Transfer Agreements
- Education

Academic Technology Transfer

- 1980 - Bayh-Dole Act
- Concerns about U.S. competitiveness
- Universities allowed to retain rights to inventions from federally-funded research
- U.S. manufacturing, preference for small businesses
- Government license, March-in rights

Technology Transfer Growth

- Little commercialization prior to 1980
- 2009 data for U.S. universities:
  - 12,109 new U.S. patent applications filed
  - 3,417 U.S. patents issued
  - 5,238 new license agreements signed
  - $2.3 billion in license income generated

Benefits to Public

- 2009 Activity
  - 658 new products introduced
  - 596 new companies formed
  - $76 billion in economic activity
- Pivotal role in creation of biotechnology industry, and contributor to development of numerous other industries

Patent Policy

- Rights assigned to University
- University responsible for patenting and licensing
- Inventor(s) share in licensing income

Commercialization Process

- Invention Disclosure to Industrial Liaison
- Evaluate commercial potential
- Secure intellectual property protection
- Identify potential commercial partners
- Negotiate license and/or research agreement
- Manage ongoing relationship

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Invention Disclosures

- Therapeutics
- Diagnostics
- Medical & Dental Devices
- Patient Assessment Tools
- Genomics (human, animal, plant)
- Software
- Hardware
- Manufacturing Processes
- Research Reagents

Evaluation

- Patentability
- Marketability
- Development Needed
- Pre-Existing Rights

Patentability

- New, Useful, Non-Obvious
- Prior Art - Publications, abstracts, presentations, etc., prior to filing of patent application
- First to invent (keep good notebooks)
- Scope of protection (e.g., specific compound vs. class of compounds)
- Dominating/background patents

Marketability

- Size of market, segments
- Competition
- Advantages, disadvantages
- Decision-makers (patients, doctors, insurers)
- Criteria (efficacy, safety, cost, speed, ease of use, switching costs)

Development Needed

- Development stage - discovery, prototype, lead compound, initial testing
- Regulatory requirements
  - Pharmaceuticals - IND, clinical trials, NDA
  - Devices - 510K, PMA
  - Agricultural – USDA Field Tests, Approval

Pre-Existing Rights

- Funded research
- Joint inventions with other institutions
- Material Transfer Agreements
  - Automatic license
  - Right of first refusal
  - Revenue sharing

Intellectual Property Protection

- Patents (right to exclude others from making, using, or selling claimed invention for 20 years from filing date)
- Copyrights (software) - protects specific code
- Proprietary materials (e.g., cell lines)
- Trademarks (e.g., Gatorade)

Licensing Strategy

- Exclusive vs. Non-exclusive
- Fields of use
- Existing company
- Start-up company

Existing Company Advantages

- Fit with product line
- Marketing channels
- Regulatory expertise
- Financial resources

Start-Up Advantages

- Focused development effort
- Can pursue multiple applications of platform technology through partnerships
- Equity participation - University benefits broadly from company success
- Entrepreneurial faculty

Start-Up Process

- Develop business plan
- Present to investors
- Investors form company and license technology
- Raise capital
- Manage conflict of interest

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Start-Up Activity

- 57 companies formed
- 24 in last 4 years
- Over $1 billion raised
- 6 companies public, 6 acquired
- Examples: Sugen (Pfizer), Smart Therapeutics (Boston Scientific), Anaderm (Pfizer)

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Recent Start-Up Companies	
Medical Center	
Atreaon	Treatment of Autoimmune Diseases
BrainScope	Brain Monitoring Technology
Cardium	Cardiovascular Gene Therapy
Constellation Pharmaceuticals	Epigenetics Research
CynVec	Cancer Gene Therapy
MET	MRI Technology
NeuoroControl	Robotic Control Systems
NeuroInterface	Brain-Machine Interface Systems
WSQ/Dental School	
Alveologic	Dental Devices
Opgen	Microbial Genome Analysis
Perceptive Pixel	Multi-Touch Screen (CNN “Magic Wall”)
Perfect Matter	Analytics for Product Formulation Optimization
PGTi	Prostaglandin Transporter Inhibitors
Spin Transfer	MRAM Technology
Toucho	Low-cost Touch Screen Technology

Trends

- Large companies interested in later stage technologies.
- University licensing to smaller or start-up companies, who develop and later partner with or are acquired by larger companies.
- Increased need for translational research and entrepreneurship.

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SoM Applied Research Support Fund

- Provides investments of up to $75K each.
- 34 investments to date. $1.6M invested.
- 10 of 34 technologies subsequently licensed.
- 15.2M in license income and $9.7M in corporate research funding generated.

NYU Innovation Venture Fund

- Created in 2010

Negotiate Agreement

- Win-Win
- Understand needs of industry and university
- Preserve core university values
- Flexibility
- Give company necessary incentive to invest, while providing fair return to university

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Agreement Terms

License

- Rights granted (exclusive, non-exclusive, field)
- Compensation (license fees, royalties, equity)
- Diligence (development plan, milestones)
- Indemnification/insurance

Research

- Research funding (budget, 54% indirect cost)
- Right to publish
- Patent new inventions, option to company

Manage Relationship

- Follow-on inventions
- Diligent development
- Lengthy development process
- Changes in company management
- Changes in company focus

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Top 10 Universities in License Income (2004-10) (Source: Association of University Technology Managers)	
New York University	$1.568M
Northwestern University	$1.238M
Columbia University	$941M
University of California System	$786M
Stanford University	$741M
Emory University	$682M
Wake Forest	$487M
University of Minnesota	$473M
University on Washington	$385M
Massachusetts Institute of Technology	$382M

Products on Market

- 24 products on market
- Remicade (RA, Crohn's Disease, AS, UC, Psoriasis)
- Sutent (Kidney & Stomach Cancer)
- Zinecard (to reduce chemotherapy side effects)
- Oracea (Rosacea)
- HIV Diagnostics
- Vascular Stent
- MRI Equipment
- CPAP device for sleep apnea
- Hip Prosthesis
- Dental Implant
- Multi-Touch Screen
- Device to generate computer imagery
- Microbial genome analysis equipment

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Multi-touch screen developed by NYU spin-off company Perceptive Pixel used as "Magic Wall" by CNN

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Products in Development

- 13 Products in Clinical Trials (Heart Disease, Cancer, Alzheimer's Disease, Parkinson's Disease, Addiction, Malaria, Wound Healing)
- Genetically Modified Crops (trees, food crops)
- Peptide-Based Drugs with enhanced stability
- Anti-Microbial Peptoids
- Prostaglandin Transporter Inhibitors
- Electrospray Deposition Diagnostic Systems
- Light-Based Device for Analyzing Samples
- Non-Volatile Memory (MRAM)
- Modeling & Graphics Software
- Low-Cost Multi-Touch Input Device

Conclusions

- Consider patent protection prior to public disclosure.
- Increased challenges – Companies interested in later stage technologies.
- Entrepreneurship and translational research must fill gap.
- Long-term positive relationships with companies key factor for success.
- NYU research benefitting patient care and society.

Inventorship, Conflicts of Interest, and Rights to Research Data

Mark Righter, Associate General Counsel,
NYU Office of General Counsel

1. Inventorship

- No discretion to scientist
  - Different from authorship
- Decided “as a matter of law”
  - Ultimately by a court (if necessary)
  - But usually by patent attorney

Wrong Inventorship is Fatal

- Law requires complete accuracy
- Too few and it is “invalid” and will be stricken
- Same result if there are too many
- Sometimes “ego” gets in the way of securing a valid patent
- Inventorship is one of the first things examined when enforcing a patent

What is the “Standard” to be an Inventor?

- Contributing to the “conception” of the invention is the keystone of inventorship
- Just being involved in reducing the invention to practice does not rise to the level of inventorship
- A grad student who works tirelessly for years on experimentation does not necessarily equate to inventorship

How Do We Prove Inventorship?

- Ultimately, written evidence is critical
  - Oral testimony or “proof” is very weak
- Laboratory notebooks are the principal means of proving inventorship
- Adherence to good standards for lab notebooks will pay off

What Makes a Good Laboratory Notebook?

- Dated daily and initialed by the scientist
- Kept in a book with numbered pages (don't leave blanks)
- Include by tape or staple key data printouts, samples, etc.
- Include witness countersignature for key developments
- Err on the side of "over-recording"
  - You'll never anticipate what will ultimately be critical

What About Industrial Co-inventorship

- Care should be taken to record interactions
  - Document dates and nature of phone calls
  - Keep written summaries of interactions, meetings, visits
- Supplying the problem, or materials used, does not amount to inventorship

Inventorship is a Moving Target

- At the time a patent is filed, “claims” are broad, trying to cover much territory
- During the patent prosecution process, claims often get significantly narrowed
  - Sometimes almost unrecognizable from the start
- Who was legitimately an inventor at the time of filing may be VERY different from who is named at the time a patent issues

2. Conflicts of Interest

- Goal: Ensure the integrity of research AND researcher
- Policy covers “actual” and “perceived,” or “apparent” conflicts of interest
  - Even the appearance of a conflict can be damaging to one’s reputation
- An ounce of prevention is worth a pound of cure

What is a Conflict?

- Basic Definition: where a financial interest influences the performance or outcome of research
  - Government agencies have defined this further
    - Eliminating minor or “deminimus” financial interests
    - Carving out some well known exceptions, such as royalties from inventions

Why Do We Care?

- If research has been unfairly influenced by the researcher's financial interest, the consequences can be VERY damaging
- In the medical/biomedical fields, the harm is obvious
- But even in other disciplines, including economic, management, IT, etc., conflicts can cause harm to others

Other Reasons to Care

- Reputation is a University's and a Scientist's most important asset
- The negative impact of a conflict of interest issue can take a university decades to overcome
- Researchers can be essentially "blacklisted" by federal agencies
- One rotten apple can spoil the whole basket

Two Key Words with Conflicts:

- 1. Disclosure
  - Transparency is critical
  - Full disclosure, as opposed to ½ the picture
- 2. Management
  - Allow University committee to make recommendations
  - Follow management plan
  - Provides insulation to researcher

How Do We Manage Conflicts?

- Protection of Students
  - Ensure the integrity of the thesis process
- Protection of Research Data

  oversight by expert researcher
- Committee will create a custom tailored conflict of interest management plan for each situation
- The plan can only be as good as the information given to the committee

Specifics of NYU Policies and Procedures

- Thresholds for conflicts:
  - govt. regs currently in flux
  - Safe line: $5,000, or 5% equity if public
  - Any equity interest if not publicly traded
  - NYU royalties are exempted
- Management processes:
  - University will create a custom-tailored management plan covering facilities, students, publications, IP (patents, software, etc.)

3. Rights to Research Data

- Why is it important?
- Who owns it?
- What are the University's Responsibilities?
- What are a Researcher's Responsibilities

Why is it Important?

- Research Data is critical to protecting intellectual property
  - Obtaining patents
  - Enforcing patents
- Government and Industrial Sponsors have rights to that data they have supported
- Research Data allows a university to preserve its integrity
  - accuracy, authenticity, primacy, etc.

Who Owns Research Data?

- University has primary ownership of research data
- Researchers have a right to use a copy of the data **Wrong Inventorship is Fatal**
  - With approval of the appropriate administrators
  - In compliance with requirements of sponsors
  - To be used consistent with NYU's rights

What are NYU's Responsibilities?

- Complying with federal and/or industrial grant or contract terms regarding retention and records
- Protecting the rights f students, postdoctoral appointees and others to access the data for appropriate purposes
- Ensuring that researchers understand other requirements regarding collecting research data (IRB, IACUC, radioactive materials, etc.)

What are Researcher's Responsibilities?

- Keeping accurate and adequate records
- Adopting an orderly and dated system for recording data
- Communicating system to all involved researchers and relevant administrative personnel
- Complying with sponsor requirements
- Assuring access to data if moving from NYU

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using

Renewable Resources

to create

BioPlastics

&

Industrial BioChemicals

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Launching SyntheZyme

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Why do this?

- A belief the technology developed is commercially viable.
- Without a company structure it can be difficult to transform an invention to product.

Technology needs to be matured

- Desire to gain some control over commercialization process.

Can I do this?

- **A University Environment that Enthusiastically Supports the idea and will help get you started!!!**
  - **Must have infrastructure in place to assist faculty.**
    - **I was approached by the University to launch a company based on the technology we developed at NYU-POLY**
    - **Given access to:**
      - **Bruce Niswander (**Director of Technology Transfer, IP Commercialization and Entrepreneuring)
      - **Richard Fishbein (NYU-POLY Board Member, Extensive merger and acquisition experience as an investment manager at Cortex)**
      - **Some seed money to pay legal and other expenses.**

Bruce and Richard put in many hours at no cost helping launch the company

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Getting started

As yourself a series of questions

10 – Provide An Industrial Benefit √

9 – Define end uses and markets √

8 – Cost < Conventional ???

7 – Replaces Conventional Product √

6 – Replacement Market > $100 million √

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The due diligence work to getting started

5 – Easy substitution by immediate users √

4 – Patents Filed (hopefully not method/process) √

3 – Competitive Products Tested (Some)

2 – Samples tested by end user (Not yet)

1 – Market Survey

As you go, are you getting excited?
Is this interesting to you?
Is you family still talking to you?
If yes, continue…..

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"Countdown to Launch"

0.9 – Grants (SBIR grants are good opportunities)

0.8 – Friends & Family (none rich)

0.7 – Angels (all in heaven)

Looking for Money!!!!!

0.6 – Find a business director (**CEO**) *who will work based on taking equity in the business*

0.5 Assess opportunities for Venture Capital (**no "seed" stage**)

0.4 – Strategic Partnerships (**JDA's seem promising**)

0.3 – Incorporation/Formation Filing (**exciting**)

0.2 – Transfer of patents from the University to the company (**University gains equity in the company**)

0.1 – Set-up a web site (**something basic**)

0.0 – **Lets go……**

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+

↓

- BioPlastic Monomers
- Industrial BioChemicals

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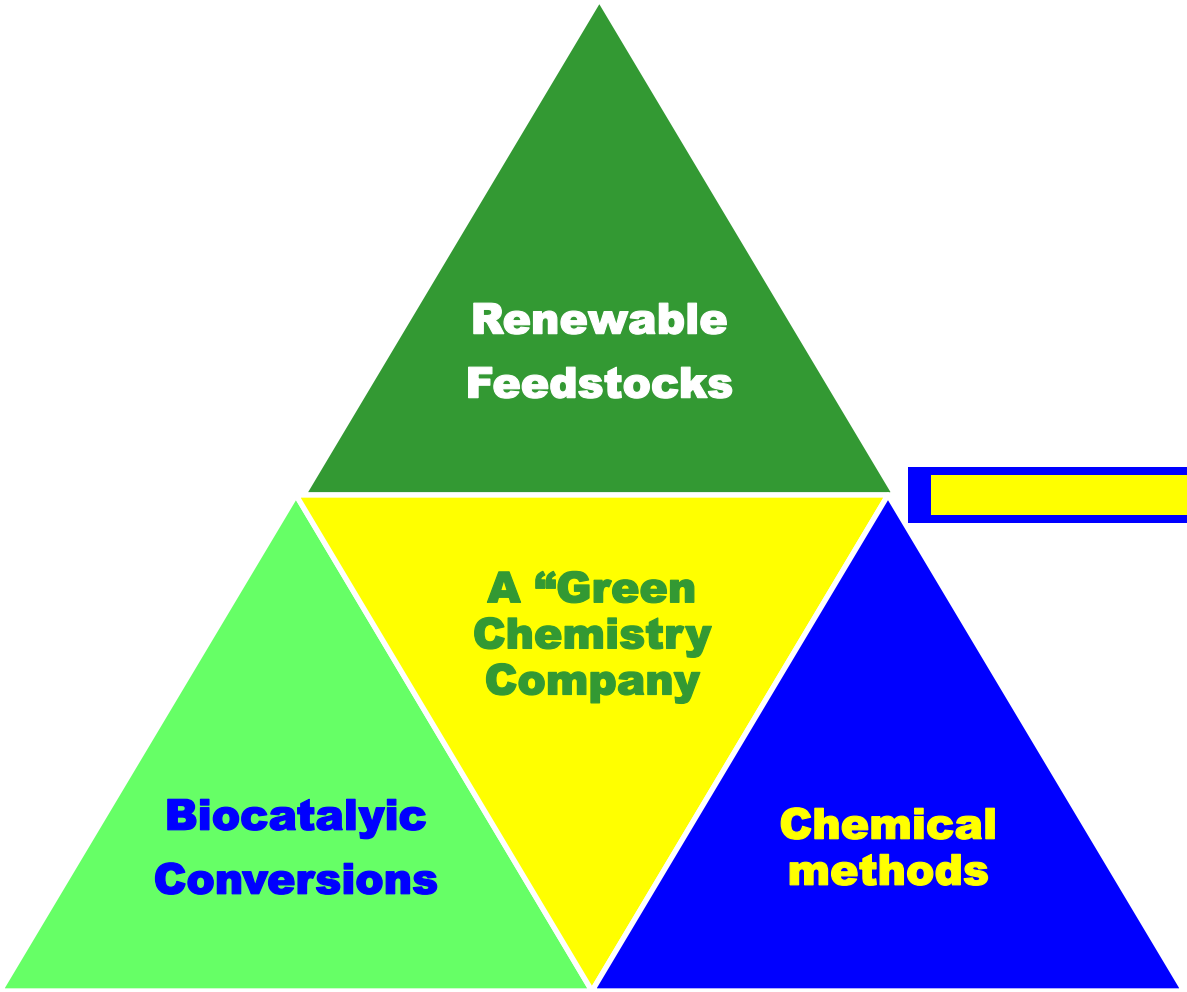
A Seed Stage Company



PRODUCTS

- Bioplastics
- Biosurfactants
- Chemicals

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SyntheZyme's Innovative Bio-Plastics

ω-Hydroxyfatty acid monomers and polymers

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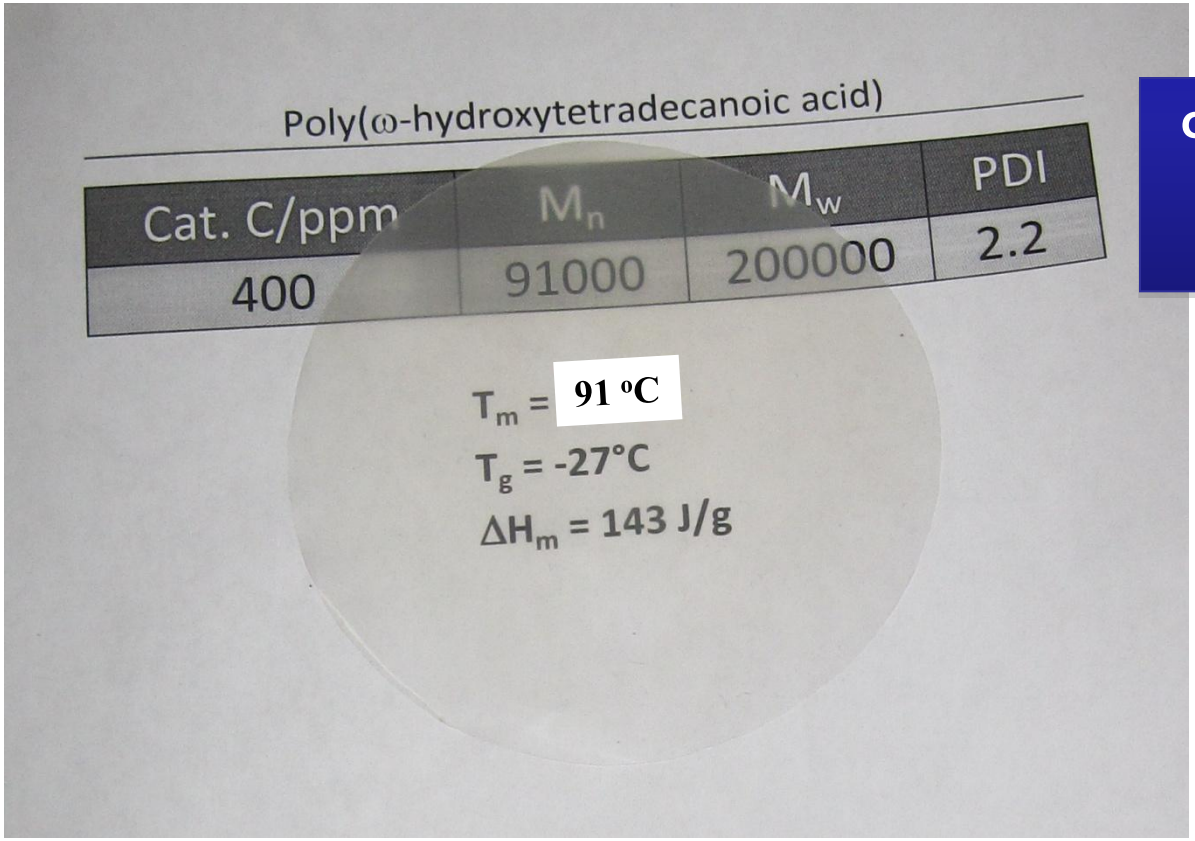
SyntheZyme bioplastics are designed for the application and for ease of processing



compression molded film

Polymerized by polycondensation of ω-OHC14 using a Ti-catalyst (200-400 ppm)

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A growing bio-plastics market

DuPont (PDO)
BASF (PBAT)
Novamont

Tellis
Biomer
Copersucar
Meridian
Tianan

PHA
$5B/yr
Addressable*

Polymers
$200B/yr

PLA
Bio-On
Cargill
Cereplast
Chronopol
FKuR Kunststoff
Mitsubishi
Mitsui
Purac

Bio - Polyethylene
Braskem

*Thomas Weisel

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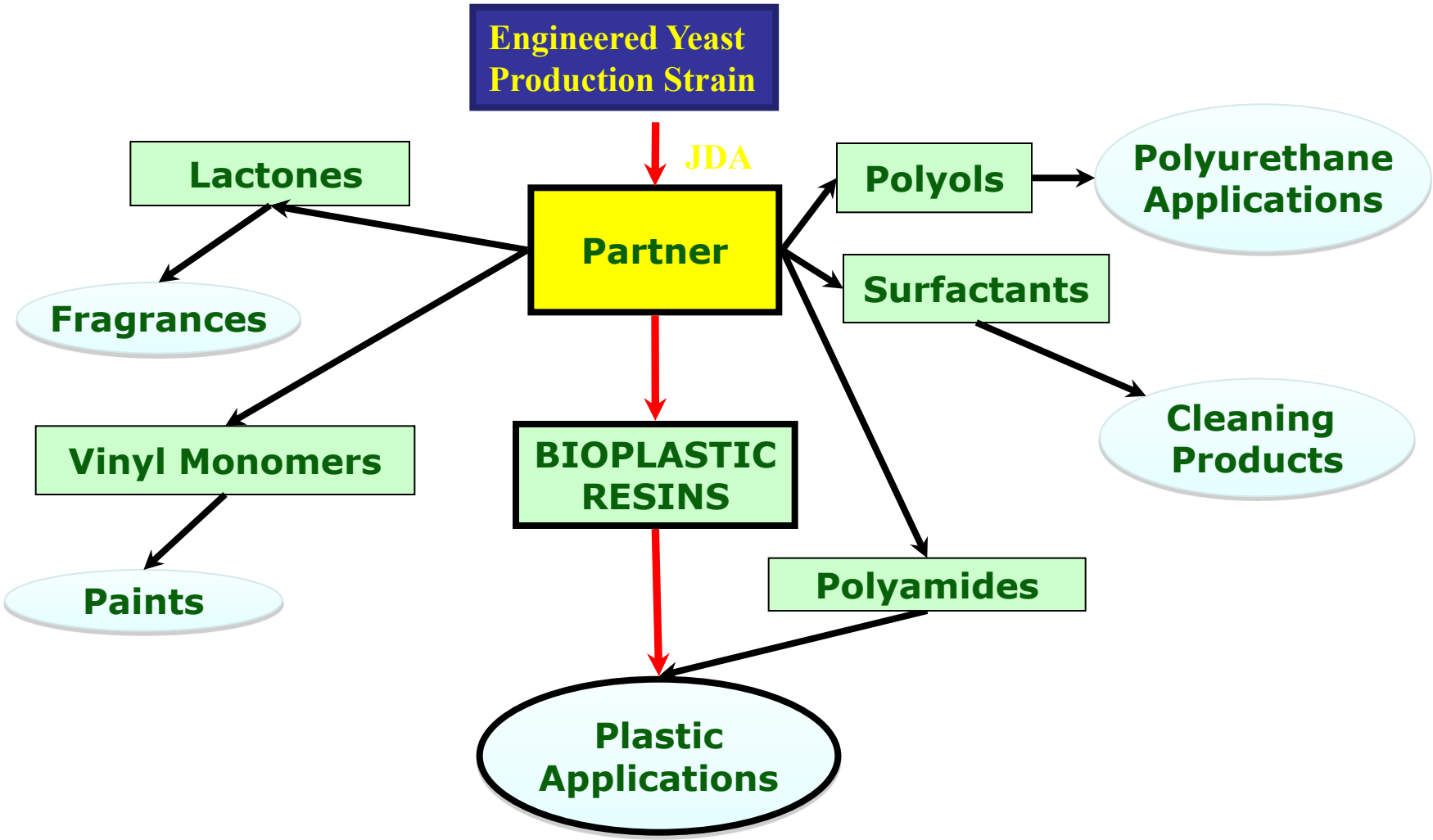
A monomer with a large potential ....



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SyntheZyme Polymer Technologies

- **Engineered *Candida tropicalis* strain for monomer productions**
  - First strain developed for industrial production of ω-hydroxyfatty acids, the monomer
  - Production in volumetric yields ~120 g/L in 55 h
  - Monomer secreted from cells simplifying downstream processing

- **ω-Hydroxyfatty monomers and polymers**
  - High molecular weight poly(ω-hydroxyfatty acid) bioplastics have been prepared.
  - SyntheZyme poly(ω-hydroxyfatty acid) bioplastics have unique and desired properties.
  - Building blocks for thermoplastic polyurethanes
  - To be used in films, molded parts etc.

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Compare your product with the competition

SyntheZyme bio-plastics vs. competition

- Competitive cost structure vs. most bio- and specialty polymers/chemicals
- Homo-, co-polymers and (reactive) blends for a wide range bio-polymer applications
- Polyethylene-like structure and behavior
- Ease of processing on standard equipment
- Fully Biodegradable

	Resin Properties	Benefits	Comments
1	Good thermal stability and shear viscosity	Ease of processing	*Shear viscosity in between HD and LD*
2	Good Melt strength	Film extrusion	*Bubble stability*
3	Good ductility	Good tear strength	*Elongation @ Break >600%*
4	Moderate stiffness	Flexibility	*Between LDPE/HDPE*
5	Rapid crystallization/ No secundary cristallization	High molding speed/ Low distortion	*Significantly better than most bio polyme*
6	Superior hydrolytic stability	Improved shelf life	*Vs. competitive bio-polymers*
7	Acceptable barrier propertie	Shelf life	*Multi-layer packaging (customer tested)*
8	Blendable	Tunable properties	*Demonstrated with PLA (Polylactic acid)*

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Make it clear to others that you understand the path forwar

A clear path forward …

GOAL	CHALLENGES/RISKS			PARTNER SKILLS
	Low	Medium	High	
Phase 1				
1 Lower costs for Increased Market Access	Faster Fermentation	Fermenting Crude Oils		Organism: Metabolic Pathway and Enzyme Engineering
2 Scale up	Bench Scale for Sampling	Process Optimization		Existing Industrial Fermentation
3 Application Development	Industrial	Application	Development	Polymers and/or Industrial Chemicals Marketing
Phase 2				
1 Lower Feedstock Costs		Alternative	Feedstocks	Metabolic Pathway and Enzyme Engineering

SyntheZyme's strategy:

- Patent technology and applications
- Use existing fermentation capacity of partner companies for scale up.
- Be flexible as to valuation scenario's, e.g. licensing, JV.

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And you understand the timetable and costs, what you can do and what you need others to do

Milestones and funding SyntheZyme

Phase 1:

- Invested to-date > $ 5MM (e.g. grants, NYU…)
- Additional Capital (Series A): $ 4.0 MM (+ R&D Grants)

Milestones	Timing (yrs)	Comments/Notes
1 Organism development	1.5	*Partner(s) identified*
2 Fermentation scale-up	0.5	*400 L*
3 Application development partner(s)	1 - 1.5	*One ongoing licensing negotiation*
4 Pilot scale up	0.8	*5-10 KT/yr; Bench scale already in progress*
5 First industrial sales	3	

Phase 2: Additional Capital (Series B) $ 7 MM

- Excluding a dedicated manufacturing facility: t.b.d. (35-40 KT/yr.)
- Excludes partner application development expense.

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Our path

- **Work hard on creating joint ventures**
  - Critical to attracting venture money
- **Make it look, feel and smell like a company**
- **Be professional in everything you do.**
  - Company presentations
  - Many many telephone conferences
  - Supplying samples in a timely fashion (at your cost)
  - Quickly and efficiently generate CDAs, MTA's
  - Getting very good at generating and protecting IP

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Our path

- **Never count on anything, just keep going.**
- **Always be honest and trustworthy (Don't overestimate what the company can do)**
- **If there is interest, make it convenient to them.**
  - We are the salesman now, they are the buyers.
- **Use criticism constructively to keep building a better story.**
- **Find good partners that are reasonable/fair to work with and that you can trust**
- **Negotiate smart. The big companies want everything but then you have nothing!!!!**
- **GOOD TECHNOLOGY WILL EVENTUALLY GET NOTICED AND SUPPORTED**

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"Potholes"

- **Customers**
  - Unrealistic desire for exclusivity & control
  - VERY long lead-times (no urgency for them)
  - Hidden specifications & agenda's
- **Funding Sources (venture and potential strategic partners)**
  - Poor understanding of technology
  - Desire education & competitive intelligence
  - Expect you to be two steps ahead of where you are (get the work done without money and then we would really like to talk with you).

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Why do all this…..

- You have taken charge of your own success
- You are clearly a little crazy, but that's okay
- Different perspective on research
  - How to choose academic research that is both interesting and high impact.
- New perspective on protecting IP from the beginning.
- Engage students in the experience/they learn about entrepreneurship and gain an industrial perspective
- You become much better at working with industry resulting in Industry funded University projects
- SBIR grants provide a new route for funding research
- Valuable life experience

QUESTIONS????