Filling The Gap Between Academic Discovery And Commercial Licensing: 
The Role Of Novel Financing And Development Structures

February 12, 2013
Healthcare And Industry Forces Are Spurring Evolution In The Way Early-Stage Innovation Is Accessed, Funded And Managed

<table>
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<th>Summary</th>
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<tr>
<td>• Trends across the healthcare landscape and within the bio/pharma industry have begun to threaten the sustainability of the industry’s research-based growth model</td>
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<td>• A significant quantity of high-quality early-stage drug candidates are required for sustainable innovation and new product commercialization, but…</td>
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<td>- Dependence on external innovation is increasing; AND</td>
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<td>- Translational research required to identify and advance product opportunities is significantly under-funded</td>
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<td>• Addressing these challenges requires novel approaches to: (i) increase investment in translational research; and (ii) improve its effectiveness &amp; efficiency</td>
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<td>• A number of novel funding &amp; collaborative structures are emerging; key themes include:</td>
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<td>- Mechanisms to reduce and/or share risk</td>
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<td>- Aligning interests and leveraging strengths of diverse sets of stakeholders</td>
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<td>- “Virtual” drug development, “fast-to-POC” strategies</td>
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<tr>
<td>• As important stakeholders in the broader biomedical research &amp; development “ecosystem”, academic institutions can play an increasingly important role</td>
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Life Science Industry Evolution Has Threatened The Sustainability Of Its Traditional Research Based Growth Model

Pharmaceutical and Biotech Industry: Evolution of the Business Model

“Casting The Model For Growth”
- Acceptable rate of innovation in large pharma coupled with golden era of biotech funding
- Managed Care enhanced access vs. the Hillary-Care threat feared
- Duopoly and monopoly protected pricing in therapeutic areas (e.g.: Novo Nordisk in diabetes, BMS in oncology)
- Barriers to entry protected by strong patents and channel specialization

“Storm Clouds Forming”
- Mega blockbuster launches … where a blockbuster went from hundreds of millions to several billion
- While NME approvals begin to slow, life cycle management compensates (e.g.: oncology “pipeline in a bottle”)
- Loosening of promotion rules (i.e.: DTC) resulted in second wave of “access” to care
- Biotech “misfires” on development; funding trough hit

“The Model Starts To Break”
- R&D productivity killing growth, niche products too small to fill the valley, life cycle management stalled by pricing
- Patent expiration wave causing a tsunami of generics over next decade
- Increased globalization, competition driving pricing down further
- Hyper asset inflation for licensing and acquisition deals

1990’s | Early 2000’s | Today
Decline In Pharma R&D Productivity Has Been Well-Documented

Source: Burrill & Company, 2010
Economic And Industry Events Accelerated Structural Change To Create Greater Dependence On External Early-Stage Innovation

Market Pressures On Product Development

**Lower R&D Spending Growth**
- Lower sales expectations for mid-large pharma/biopharma
- Reduced funding availability for emerging biopharma
- Only modest improvement

**Near- to Long-Term Pressures**
- Moderate growth in quantity of late stage pre-clinical to clinical activity
- Reduced rate of clinical approvals
- Shifting composition of pre-clinical activity to biologics
- Near-term focus of resources on later-stage clinical programs
- Longer-term shift to “Fast to POC” early dev. model may be underway

**Pipeline Productivity & Mix**
- Pipeline Prioritization

Source: TFG LLC Primary Interviews
Based On Current Estimates, ~9 Drug Candidates Must Enter Clinical Development Each Year To Drive Launch Of 1 New Molecular Entity (NME) Per Year

Both quality early-stage drug candidates – and a significant quantity of them – are required for sustainable innovation and new product commercialization

Yet, Translational Research, The Critical First Step In Moving Scientific Knowledge Toward Clinical Application, Is Significantly Underfunded

Despite Historical Funding Challenges, Small Innovator Companies, Often Operating In An “Ecosystem” With Academia, Have Been The Source Of Many Novel Drugs

Sources of New FDA-Approvals, 1998-2007

It is tempting to speculate that drug discovery has become “over-industrialized”, with smaller innovator companies less susceptible to this trend.

“Over-Industrialization” of Drug Discovery

**NME’s (1999-2008) by Route of Discovery**

<table>
<thead>
<tr>
<th>Route of Discovery</th>
<th>Phenotypic screening</th>
<th>Target-based screening</th>
<th>Modified natural substances</th>
<th>Biologics</th>
</tr>
</thead>
<tbody>
<tr>
<td>First-in-class drug</td>
<td>37%</td>
<td>17%</td>
<td>7%</td>
<td>25%</td>
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<tr>
<td>Follower drug</td>
<td>83%</td>
<td>30%</td>
<td>13%</td>
<td>19%</td>
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</tbody>
</table>

**Commentary**

- Advances such as genomics, combinatorial chemistry and HTS have lead to rapid increases in the number of drug targets and compounds that can be screened.
- Broader biological understanding of targets, pathways, pathophysiology may have lagged behind these industrialized, reductionist “magic bullet” approaches.
- Historical review shows that phenotypic screening was behind the discovery of more novel first-in-class drugs than target-centric approaches, suggesting that the biological perspective cannot be de-emphasized.

Bridging The “Valley Of Death” Is Likely To Require Novel Approaches To Both Increase Investment In Translational Research And Improve Its Effectiveness

Key Challenges to Bridging “The Valley of Death”

Increased Investment

• Even with recent development such as creation of NCATS (National Center for Advancing Translational Sciences) within NIH and increasing investment by nonprofits, entirely new investment vehicles may be required to make significant amounts of new capital available for translational research.

Enhanced Effectiveness & Reduced Risk

• Given that the pool of available capital for investment in early-stage and translational research is likely to remain relatively stable over the near- to mid-term, there is a need to experiment with novel collaborative and funding structures that reduce risk and improve efficiency / effectiveness of translational research.
It Has Recently Been Proposed That Large, Diversified Megafunds Could Mitigate Risk And Provide An Acceptable Rate Of Return For New Classes Of Investors

“Drug Discovery Backed Securities” Megafund Concept

- Create large diversified portfolios of $5-$30B allocated to ~150+ projects
- Structure as combination of equity and securitized debt to (i) access large, long-term sources of capital, such as pension funds, insurance floats, etc.; and (ii) enhance equity returns through use of debt
- Use external/virtual drug development model -- low fixed costs and freedom to kill programs early
- Profits result from selling/out-licensing/partnering successful drugs

BioPontis Alliance Is A Virtual Product Development Company That Links Key Stakeholders In A Collaborative Structure To Reduce Risk And Increase Efficiency

Overview: BioPontis Alliance Approach

- Bring together (1) university inventors and their institutional interests with an (2) experienced translational development capability and (3) investors
- Apply industry science best practices
- Utilize highest level of expertise available, accessed from any source a 'biocloud' of networked experts.
- Develop drug candidates as projects, not in independent companies… **focus capital on science NOT company formation.**
- Develop all assets in alignment with the ultimate licensor of pharmaceutical products – pharmaceutical companies – in order to meet market demand

Source: BioPontis Alliance Web Site
Internal Pharma Venture Funds Are Another Vehicle For Financing Translational Research; Creative Variations Exist, Such As Eli Lilly’s “Mirror Funds”

Eli Lilly “Mirror Funds”

- Eli Lilly contributes up to 20% of capital into an independently managed fund with venture capital investors providing majority of funding
- The funds in-license early-stage drug candidates from Eli Lilly and other companies, and pursue a virtual drug development model
- Lilly’s independent, fast-to-POC Chorus unit is available for development support
- Lilly shares in profits, retains rights to buy back its own molecules, as well as to evaluate and acquire a set number of externally-sourced compounds
- Over 5-7 years, funds generate an external pipeline that “mirrors” internal development

Source: company website; Nature Biotechnol. 29:774-775 (2011)
**GSK CEEDD Is A Division Of GSK R&D That Seeks To Foster Early Drug Development To Ensure Exclusive Options Of High Quality Clinical Pipeline**

### GSK Center Of Excellence For External Drug Discovery (CEEDD) Profile

**Overview & Objectives:** GSK R&D department dedicated to forming external alliances leading to late-stage internalization into GSK development program. Applicants can contact CEEDD directly.

**Investment Focus:** Focus on batch-acquiring *preclinical and phase I* leads from small-medium biotechnology companies. Wide TA distribution, including oncology, CNS, inflammation, GI.

**Partners / Portfolio Companies:** ChemoCentryx; Chroma Therapeutics; Concert Pharmaceuticals; Ligand; Neurosearch; OncoMed Pharmaceuticals; Prosensa; Ranbaxy; Targacept; Theravance

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<tr>
<th>Key Offerings</th>
<th>Typical Deal Structure</th>
<th>Value to Partner</th>
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<tr>
<td><strong>Consulting Services</strong></td>
<td><strong>Initial payments to drive growth</strong> (direct funding and/or purchase of stock) range from $25-50M</td>
<td><strong>CEEDD will take large portion of portfolio, defined around a TA, not just one compound at a time</strong></td>
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<tr>
<td>– Technology, drug development</td>
<td><strong>Milestone payments, ranging to &gt;$1B total upon reaching clinical successful phase II, incremented by development phase</strong></td>
<td><strong>No internal pipeline so CEEDD only focuses on partner’s pipeline development</strong></td>
</tr>
<tr>
<td><strong>Access to GSK research resources</strong></td>
<td><strong>Exclusivity – deals include exclusivity to option and commercialize discoveries that reach clinical milestones.</strong></td>
<td><strong>Long term financing based on clinical milestones, coupled with strategic guidance to get there as efficiently as possible</strong></td>
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<td>– GSK's large compound library</td>
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<td>– Preclinical development services via Scinovo</td>
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<td>– Alliance companies must buy into these services</td>
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<tr>
<td><strong>Direct Funding</strong></td>
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<tr>
<td>– Initial payments to drive growth</td>
<td></td>
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<tr>
<td>– Milestone payments</td>
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<tr>
<td>– Eventual licensing deals</td>
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</table>

Source: Company website
Scinovo Is A Division Of GSK That Seeks To Support Early Drug Development For Companies With Whom GSK Has Signed Deals

**Scinovo (GSK) Profile**

**Overview & Objectives:** Unit within GSK R&D dedicated to working with early-stage external partners to accelerate preclinical development

**Investment Focus:** small-medium biotechs with early-stage product candidates

**Partners / Portfolio Companies:** N/A

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### Key Offerings

- **Consulting Services**
  - Preclinical science and drug development

- **Access to GSK resources**
  - Sourcing options to complete work packages
  - Technology and knowledge of 3000 GSK preclinical development experts
  - Global network of CRO/CMO suppliers

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### Typical Deal Structure

- Nonclinical support model for GSK’s option-based, early-stage partners
- Consultancy and delivery of work support is only provided to assets that are part of a deal with GSK
- Scinovo’s goal is not to make a profit, but rather help a compound progress and accelerate preclinical development

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### Value to Partner

- Access to GSK’s nonclinical drug development consultants
- Access to GSK’s nonclinical science and technology expertise
- Ability to leverage GSK’s global preferred supplier network
- Onepointsm access to the global scientific resources and regulatory expertise of GSK, channeling best practices, best pricing, and highest service quality into each development collaboration

Source: Company website
Puretech Ventures Focuses On Investing & Commercializing Compounds / Technologies In Areas Of High Unmet Need Including Preclinical Development

### Overview & Objectives:
Puretech specializes in company creation by identifying novel technologies, creating companies to drive discoveries into clinical research. Ideas can be submitted to Puretech, in addition to their own targeting.

### Investment Focus:
**Early-stage (discovery)** novel therapeutics, medical devices, diagnostics, & research technologies with high unmet needs, predictive technologies in preclinical studies.

### Partners / Portfolio Companies:
- Gelesis, Endra, Mersana, Neovasc, Vision Sense, Vascular Biogenics, Solace Pharma, Satori, Enlight Biosciences

### Key Offerings
- **Direct Funding**
  - Initial payments to drive growth
  - Designing Preclinical & Clinical plan including milestones
  - Milestone payments
- **Proactive targeting**
  - Puretech prides itself on being able to identify technologies/products at very early stages - prior to publications
- **Company Formation**
  - Management oversight to further commercialize technology

### Typical Deal Structure
- Historical investments have provided seed funds, series A & series B funds to incubated companies typically around $3-$5M with Puretech partners as Founding CEOs
  - Satori Pharma $3M - Seed funding
  - Follica $5.5M & $11M (2 & 3 investors respectively) – Series A & Series B funding
  - Satori Pharma $22M (4 investors) – Series A funding
  - Solace Pharma $15M (3 investors) Series A funding

### Value to Partner
- Expertise of firm in scientific and strategic areas could be key due to deep involvement with various ventures and exposure to technologies at very early stages.
- Potential access to technologies earlier due to exposure via Enlight Biosciences (Initiative with Merck, Pfizer & Lilly to identify & commercialize pre-competitive technologies to increase POS)

Source: Company website, News reports
## Vanderbilt Center for Neuroscience Drug Discovery

### Description

- Mission: promote translation of advances in basic science to novel therapeutics by **de-risking efforts focused on novel approaches** for treatment of serious brain disorders
- Includes all major infrastructure for drug discovery traditionally found only in industry settings
- Let by veteran drug discovery scientists

### Approach

- License agreement in pre-negotiated collaborative partnership
  - High-throughput screening internally followed by early target validation
- License leads discovered in University:
  - Leave open door for early lead optimization in academic setting to meet pharma requirements; common mechanisms is right of first refusal

### Partnerships

- **Janssen, Schizophrenia:**
  - Janssen provides $10M in research funding through 2012 for discovery and optimization of novel compounds; $100M in potential milestones
- **Seaside Therapeutics, Fragile X:**
  - 2008: $4.5M seed funding to discover and develop M1R antagonists
  - 1/2010: renewed deal
- **Michal J Fox Foundation – Parkinson’s Disease**

Source: VCNDD.com
Academic Drug Discovery Efforts Appear To Be On The Rise

Growth of Academic Drug Discovery

Mission & Objectives

Mission:
ADDc's mission is to facilitate collaboration and exchange of knowledge amongst academic drug discovery scientists in order to accelerate the development of new therapeutics to enhance the lives of patients.

Objectives:
- Establish a network of academic drug discovery scientists and programs from around U.S.
- Exchange know how and expertise related to - drug discovery programs, technologies, faculty engagement, industry partnerships, contractual arrangements
- Create a central repository website of drug discovery center information
- Provide education and training for students and for universities interested in establishing centers
- Advocate/Advisory to NIH and other funding agencies
- Establish (bi)annual meeting and programs

http://www.addconsortium.org
Trends In Early-Stage R&D Funding Create Opportunities For Biomedical Research Institutions To Become More Integral Stakeholders In Drug Discovery

Evolving Roles in R&D “Ecosystem”

- Source of knowledge/insight regarding disease biology, pathways, targets
- Site of clinical trial performance
- Generation of testable therapeutic hypotheses & early candidate therapeutic agents
- Direct partner in translational research to generate clinical-stage drug candidates
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Frankel Group Has Been Providing End-To-End Strategic Analytic And Advisory Services To The Life Sciences Industry For 18 Years

Practice Profile

• Founded in 1993

• Exclusive life science focus

• Experienced staff

• Diverse client base

• Broad analytic and strategic services

• Customized engagements and solutions…no “off-the-shelf” recommendations

• 90% client retention rate

• 20% X 10 year CAGR
## Services Span The Life Science Value Chain

### Scope of Practice

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<td>Org / technology capability review</td>
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<td>Platform and business model investment recommendation</td>
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<td>Forecast and valuation</td>
<td>Channel strategies</td>
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<td>Transactional assistance</td>
<td>Franchise strategy development</td>
<td>Pricing and reimbursement</td>
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<td>Geographic expansion</td>
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<td>Loss of exclusivity management</td>
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<td>Franchise strategy</td>
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Experience Base Is Broad, Spanning Multiple Therapeutic And Technology Segments

**Experience Base (Examples)**

**Therapeutic Area Experience**
- Autoimmune
- Cardiovascular
- Dermatology
- Endocrinology
- Hematology
- Infectious Disease
- Inflammatory
- Gastrointestinal
- Metabolics

**Technology Platform Experience**
- Therapeutic Constructs
  - MAb
  - Protein/peptide
  - Small molecule
  - Prophylactic vaccine
  - Therapeutic vaccine
- Drug Forms
  - SOD (IR, MR)
  - Non-SOD oral
  - Injectable / infusion
  - Transdermal (patch, topical)
  - Inhalation
- Emerging Technologies
  - Cell therapy
  - Tissue engineering
  - Gene therapy
  - Genomics
- Diagnostics
  - Molecular
  - Imaging
  - Serum
- Data
  - HIT / bioinformatics
  - Computational biology

**Experience Base (Examples)**
- Nephrology
- Neurology
- Oncology
- Pain
- Psychiatry
- Respiratory/Allergy
- Rheumatology
- Virology
- Women’s Health
Client Base Is Also Broad

### Biopharma Clients (Examples)

<table>
<thead>
<tr>
<th>Pharma</th>
<th>Specialty / Generic</th>
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<tr>
<td>AstraZeneca</td>
<td>Omrix</td>
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<td>Bayer</td>
<td>Mallinckrodt</td>
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<tr>
<td>AMYLIN</td>
<td>Sandoz</td>
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<tr>
<td>Baxter</td>
<td>MedImmune</td>
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<tr>
<td>Cephalon</td>
<td>IMPAX</td>
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<tr>
<td>Dainippon Sumitomo Pharma</td>
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<td>Forest Laboratories, Inc.</td>
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<td>Abbott</td>
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<td>sanofi aventis</td>
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<td>Inspiration</td>
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Client Base Is Also Broad

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<td><strong>Emerging Pharma</strong></td>
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<td><strong>Device / Diagnostic</strong></td>
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<td>BRACCO LIFES FROM INSIDE</td>
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<td>molecular Insight Pharmaceuticals</td>
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### Approach

#### “The Business of Science”
- Emphasis on mastering the scientific, technological and clinical underpinnings of every analysis
- In-depth investigation of disease etiology, pathophysiology, pathways and molecular targets
- Critical evaluation of “state-of-the-science” and identification of value-driving trend in innovation

#### “The Science of Business”
- Scientific assessment linked with comprehensive evaluation of commercial opportunities and investment requirements
- Findings are supported by robust, data-driven analytics
- The ultimate goal of Frankel Group is to create shareholder value for our clients
The Strength Of Our Organization Is Built Upon Quality Of Staff: >80% With Graduate Degrees

**Our People**

- **Staff holds MBAs, MDs, MPHs, MHAs, PhDs**

- **Sample institutions including** Harvard, Yale, Penn, Columbia, Stanford, Dartmouth, Cornell, Berkeley, Hopkins, Carnegie Mellon, Chicago, Duke, Emory, Boston College, NYU, BYU, Michigan, Texas, Connecticut

- **Experience across the value chain:**
  - bench research & clinical development
  - planning, strategic planning and business development,
  - commercialization (marketing and field sales)

- **Robust market analytics/research**
  - (secondary, qual/quant primary)
  - capabilities are fundamental to all of our engagements
Primary And Secondary Research Efforts Are Global

Our Project Primary & Secondary Research Footprint

- Primary research can include KOLs, community physicians, payer and other channel stakeholders across country markets
  - Frankel Group database of ~6K
  - Global partner reach (w/FG projects completed)
- Secondary research coverage is robust
  - Syndicated reports & databases
  - Scientific journals
  - Various databases (e.g., ADIS Insight)
  - Relevant medical associations and organizations
Clients Come To, And Stay With Frankel Group Due To Proven Track Record

**Client Value Proposition**

1. Specialized Life Science expertise
2. Focused teams delivering consistent quality work
3. Senior management level involvement
4. Advisory services across the value chain
5. Creative, actionable recommendations

“The frankelgroup team provided a level of service, content expertise, and analytic depth that we have seldom seen in our interactions with outside firms, including the large ones.”

- frankelgroup Client