

# The Amgen Approach to Overcoming Licensing Challenges and Building Alliances

Thomas D. Zindrick



AMGEN<sup>®</sup>



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# The Company

AMGEN

- Founded in 1980
- World's largest biotech company
- \$8+B\* in revenues in 2003
- Global presence
- Ranked #1 in R&D spending in the biotechnology industry by MIT's Magazine of Innovation

\*Wall Street estimates, actual results may vary

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# Long History of Licensing Activity



## Development of Partners' Products:

ABGENIX	ABX-EGF, human antibodies
ACADIA	Chemical genomics
ALANEX	Small molecules
ARRIS	Small molecules
BIOFOCUS	Ion channels
BIOVITRUM	BVT.3498 for diabetes
CAT	Human antibodies
CELERA	Genomics database
CELLTECH	Target for osteoporosis
GENENTECH	TRAIL
GENMAB	IL-15
GENOME THERAPEUTICS	Drug discovery bone diseases
GLYCOREX	Carbohydrate chemistry
GUILFORD	Neuroimmunophilins
IMMUNOMEDICS	Epratuzumab
INFINITY	Small molecules
ISIS	Antisense drug candidates
MEDAREX	Human antibodies

NEOGENESIS

NIH

NPS

PHARMACOPEIA

PRAECIS

ROCKEFELLER UNIV

REGENERON

TULARIK

UNIV of TENNESSEE

VANDERBILT UNIV

Drug discovery

Palifermin

Cinacalcet HCl

Small molecules

Plenaxis

Leptin

BDNT & NT3

Cancer amplified gene targets

Ab

CD148 Ab

## Development of Amgen's products:

KIRIN

J&J

NUVELO

ROCHE

VIACELL

YAMANOUCHI, INTERMUNE

ESPO (epoetin alfa)  
GRAN (Filgrastim)

Procrit (epoetin alfa)

Alfimeprase

NEUPOGEN (Filgrastim)

Cell Therapy Products

Infergen

# Benefits of Licensing

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- Licensing and partnering transactions can
  - generate revenues
    - + During first nine months of 2003, Amgen generated \$387 million in revenues from corporate partnerships and royalties.
  - validate scientific efforts
  - build expertise
  - share development risk

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# Strategic Alliances Have Strengthened Amgen's R&D

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## Molecule/Collaboration

## Source

Cinacalcet

NPS

KGF

NIH

BVT.3498

Biovitrum

Oncology research  
collaboration

Tularik

SELECT EXAMPLES

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# Licensing is a Priority at Amgen

AMGEN

- Searches aggressively and globally for outside innovation
- Has an experienced, focused team of licensing professionals
- Prioritizes licensing activity by therapeutic area
- Places a premium on speed and efficiency in evaluation and decisions - a competitive advantage
- Makes licensing “everyone’s business”

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# Prospecting Focus

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## Oncology

- Novel therapeutics
- Supportive care agents
  - Cachexia
  - Anemia
  - Neutropenia
  - Emesis
  - Mucositis

## Inflammation

- Rheumatoid Arthritis
- Psoriasis
- Systemic Lupus Erythematosus
- Inflammatory Bowel Disease
- Multiple Sclerosis
- Asthma/COPD
- Osteoarthritis

## Hematology/Nephrology

- Stem cell mobilization
- Hematopoiesis
- Renal disease
- Hyperparathyroidism

## Metabolic Disorders

- Diabetes
- Metabolic Syndrome
- Osteoporosis

## Cardiovascular

- Thrombosis
- Dyslipidemia

## Neuroscience

- Pain
  - Neuropathic
  - Inflammatory
- Alzheimer's Disease
- Parkinson's Disease

## Discovery & Technology

- Drug discovery collaborations
- Chemical entity collections
- Diagnostics/Biomarkers
- Novel antibody platforms
- Assay biologicals/devices
- Structural biology and computational tools

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# Seeking Opportunities at All Stages and in All Modalities

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- Late-stage and marketed products that can be promoted to oncologists, rheumatologists, dermatologists and hospital-based physicians
- Early clinical and preclinical candidates in our areas of disease focus
- Research stage collaborations on targets of interest
- Proteins, antibodies and small molecules

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# General Product Criteria

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- Novel mechanism
- Well-validated target
- Good IP position
- Well-characterized pharmaceutical properties
- Potential to significantly improve the lives of patients suffering from grievous illnesses

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# Presenting an Opportunity — What to Include

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- What is it?
- Is it a strategic fit?
- The first non-confidential information
  - What is modality (protein, antibody, small molecule, . . .)?
  - What is mechanism?
  - What is evidence for role in disease?
  - What is differentiating?
  - What kind of data exists (in vitro, cells, animals, tox, . . .)?
  - What is its potential use?

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# Amgen's Evaluation

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- What will have to be done or spent if we license?
- Building a development plan with
  - Incomplete information
  - Staged information (patents)
  - New areas to evaluate; help in getting up the learning curve
  - Lack of predictability from preclinical models
- What are the risks?
  - How to treat team members' concerns: a show stopper versus a warning
  - How to sum up risks (how many separate bad things will come true?)
  - Want to warn but not prevent a reasonable deal

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# Amgen's Evaluation (cont'd)

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- What is the value potential?
  - Unmet need or underserved patient population
  - First-to-market / competition
  - Patent Landscape
    - + Patents pending or issued
    - + Breadth of claims; geographic coverage
    - + Additional 3<sup>rd</sup> party IP, necessary or desirable

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# Patent Protection is Critical to Creating Value

AMGEN

- Creating a strong and comprehensive patent position alleviates risk
- Amgen takes systematic approach to obtaining comprehensive patent protection for drug candidates
- Amgen has developed a reputation as an aggressive enforcer of its patent and contract rights

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# Patent Protection is Critical to Creating Value (cont'd)

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- Strong patent protection and aggressive enforcement preserves value by effectively excluding competitors from the marketplace
  - e.g., On Jan. 6, 2003, U.S. Court of Appeals upheld lower court's decision that TKT and Aventis infringed Amgen's patents relating to erythropoietin products and processes for making erythropoietin. During the first nine months of 2003, Amgen generated \$2.8 billion in revenues from its erythropoietin products.
  - Strong worldwide IP portfolio is key to Amgen out-licensing success.

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# What an Amgen Deal Looks Like

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- Deal structures vary and reflect the opportunity, the risk factors and the needs of the collaborator
  - Capitalize on strengths and expertise of both parties
  - Tiered royalties enable collaborator to participate in upsides
  - Profit sharing may be used where parties are sharing development and/or commercialization costs
  - Equity investments signal a commitment to Licensor, not just deal; increases visibility to investors
  - Commercialization rights may include co-promotion, product detailing
- We prefer global rights to enable a global development plan
- For co-development, co-promotion deals, alignment of vision and financial flexibility are important

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# Defining “Successful” Deal

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- The risks are appropriately identified
- Both parties are treated fairly
- Agreement is drafted with evenhandedness
- IP is appropriately protected and managed
- The deal structure does not hinder the team or the objectives of the parties
- The deal structure accommodates changes
- Both sides work well together

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# Licensors Need to Identify the Right Partners

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- Partners who can maximize value
  - Fast-moving, nimble and well-resourced
  - Existing therapeutic area franchise
  - Effectively creates and tenaciously defends intellectual property
  - Track record of success
  - Experienced, with precedent of long-lasting partnerships
  - Synergistic relationship (e.g., corporate culture and complimentary capabilities)

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# The Amgen Difference: Scale of a Large Company & Nimbleness of a Smaller One

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## Big Pharma

- Large and complex organization
  - 40,000+ employees
  - > \$15B in revenues
- Enormous breadth
  - 50+ products and 50+ programs
- Near-term financial pressures
  - Patent expiries
  - Revenue and EPS growth challenge

## Amgen

- Large and nimble organization
  - 13,000 employees
  - \$8+B\* in revenues
- Focus
  - 5 products and 35 programs
- Strong near-term financial condition
  - No near-term patent expiries
  - Strong revenue and EPS growth

- Amgen brings Size, Nimbleness, Experience and Commitment
- Partners bring innovation to meet our growth aspirations
- Together, Amgen and its partners work together to build world-class brands that dramatically improve people's lives

\*Wall Street estimates, actual results may vary

# Amgen Is Flexible in Its Partnership Approach

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## Equity Investment

- **Tularik:** Purchased \$35M of newly issued stock with commitment to purchase an additional \$40M over next 3 years

## Milestone/ Royalty Payments

- **NPS:** Provided milestone payments for development of Cinacalcet HCl along with royalties on future sales

## Broad Research Collaboration

- **Biovitrum:** In-licensed BVT .3498 and funding 3-yr research program to develop additional compounds

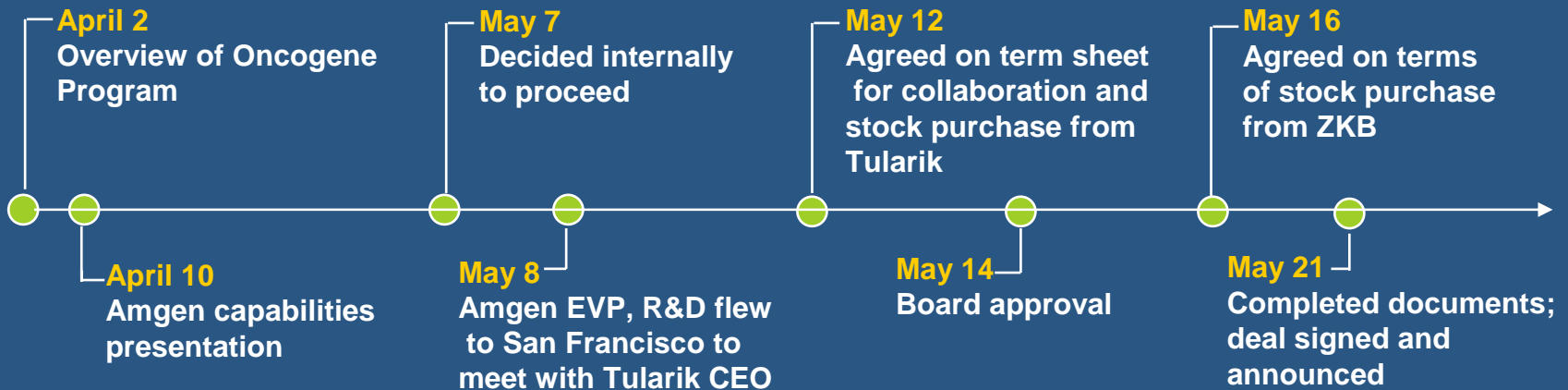
## Acquisition/ Other

- **Immunex:** Purchased for \$10.3B in cash and stock
- **Abgenix:** Shared development and commercialization costs for ABX-EGF

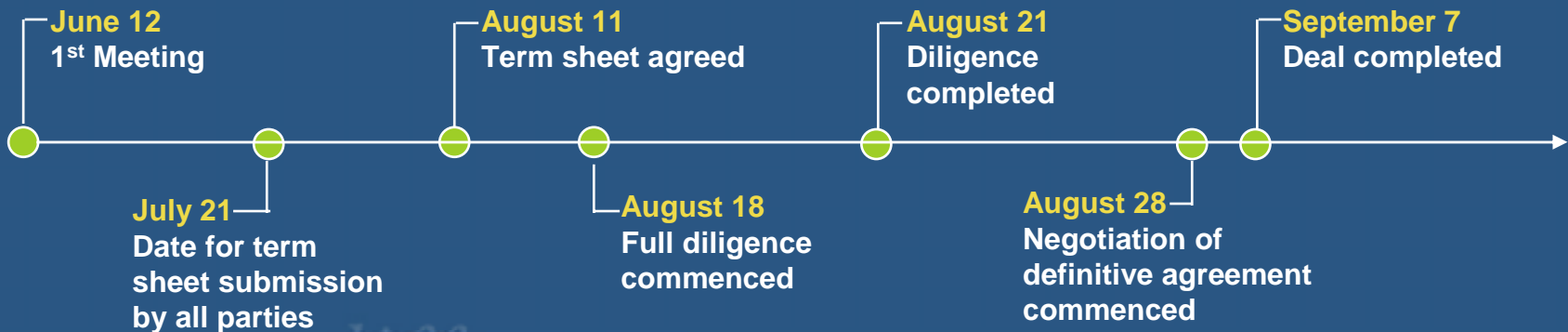
# Our Partnerships with Biovitrum and Tularik Demonstrate Our Agility

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## Timeline of Recent Amgen/Tularik Negotiation



## Timeline of Recent Amgen/Biovitrum Negotiation



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# After Signing the Deal (Alliance Management)

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- Amgen has newly expanded its Alliance Management Team
- Governance
  - Joint committee structure based on stage of development
  - Premium on crisp decision making so that research, development and commercialization are not delayed
- Dispute Resolution
  - Allow committee autonomy, but provide the Party primarily responsible for function to have tie-breaker vote
  - Limit scope of issues raised to senior management
  - Executives need to intervene when friction arises from misaligned objectives

# Final Thoughts

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- Collaborative agreements manage the risks and rewards of drug development
- Successful collaborations maximize the therapeutic and commercial potential of licensed products
- Value created by being first to market and maintaining exclusivity in the marketplace
- Amgen is seeking significant licensing opportunities to build world class brands that dramatically improve people's lives

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# For More Information

Visit Amgen's website – [www.amgen.com](http://www.amgen.com)

**AMGEN**  
Dramatically Improving People's Lives

Partnership with Amgen

Amgen searches aggressively and globally for outside innovation. Our Licensing group focuses on identifying, evaluating, and/or licensing product candidates to enhance our product pipeline. We actively seek both pre-clinical and clinical candidates within our therapeutic areas of interest.

We are also interested in access to novel technologies that complement our research capabilities. In addition, we seek technological advancements that will allow for more efficient and effective methods of drug discovery and development.

**Amgen as a Partner**  
Our co-licensing efforts focus on both industry and academia. They are an important part of our ongoing search for innovative products and technologies.

**Amgen's Therapeutic Areas of Interest**  
Amgen's strategic direction for partnering is directed by five therapeutic areas being. The teams focus on oncology, inflammation, neuroscience, nephrology, and metabolic disorders. We are also open to other opportunities and technologies having novel science and compelling commercial potential.

**Having your Licensing Opportunity Reviewed at Amgen**  
Amgen is interested in evaluating therapeutic product candidates and technologies that complement our product development strategy.

The Licensing Department at Amgen may be contacted in the following ways:

- Via e-mail: [NewProducts@amgen.com](mailto:NewProducts@amgen.com)
- Via fax: (855) 499-7573

Aranesp  
Entrel  
EPOGEN  
Kineret  
Neulasta  
NEUPOGEN  
Novantrone

Or contact via e-mail:

[NewProducts@AMGEN.com](mailto:NewProducts@AMGEN.com)