Valuing Intellectual Property

Venture Center, Pune, India

November 19, 2022

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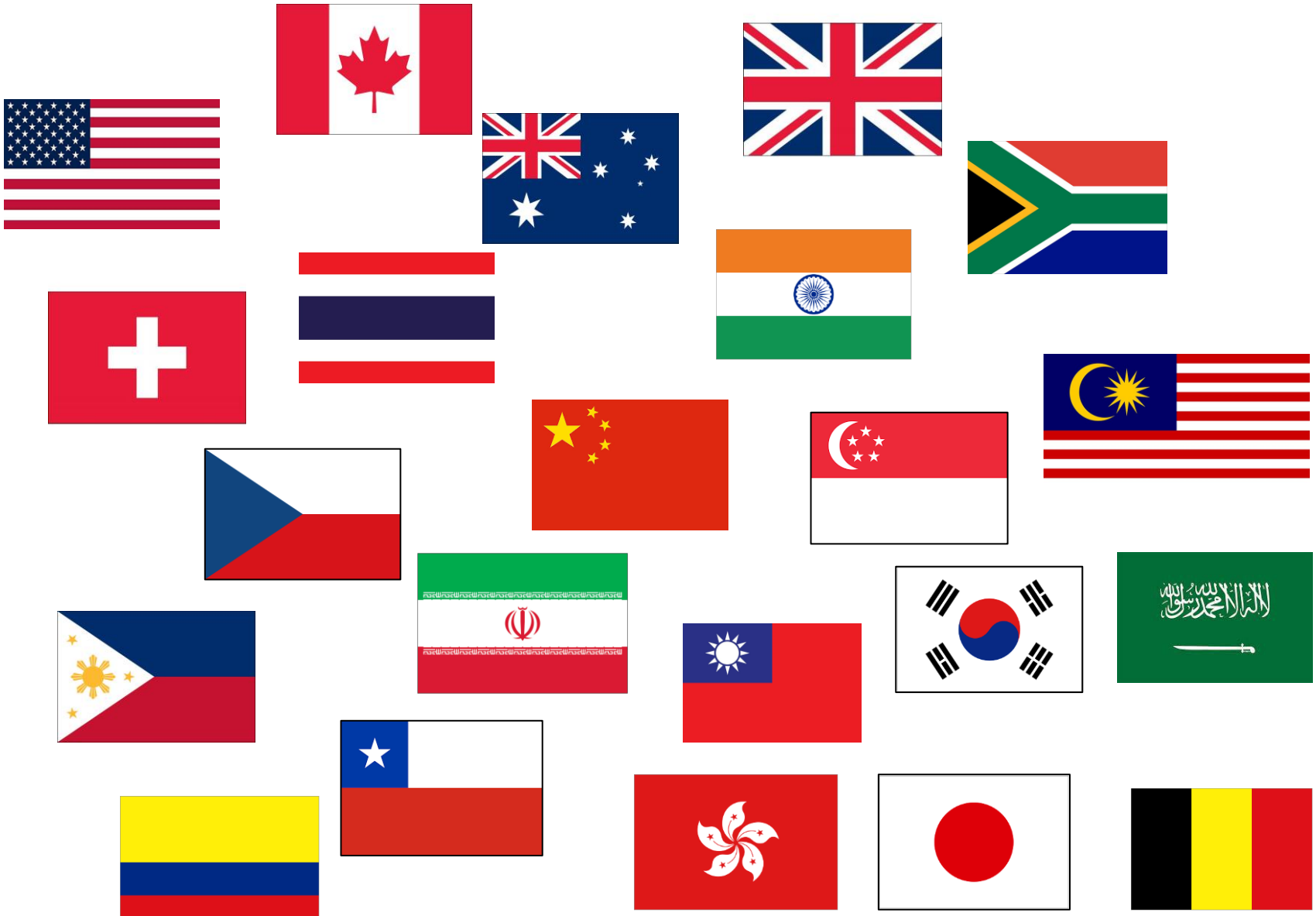
President

FOCUS IP GROUP, LLC



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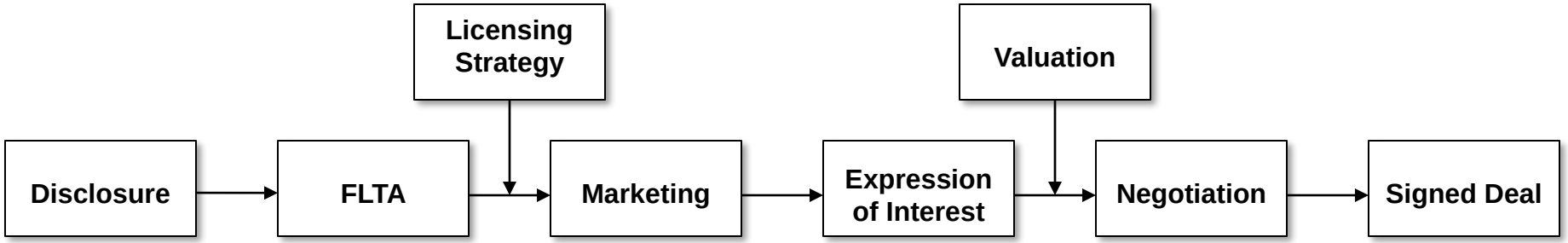
The Technology Transfer Process



Agenda

- Valuation vs. Pricing
- How value is extracted in a license
- Risk and Value
- Valuation Methodologies
  - Cost
  - Rules of Thumb
  - Industry Standards – Comparables
  - Discounted Cash Flow / Net Present Value

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As You Start off on a License Negotiation…

- What is the Product?
  - New product
  - New market
  - Disruptive?
- How is value added?
  - New use
  - New product feature
  - Lower cost
  - Blocking competition?
- What is the business model for revenue generation?
- What is the market and competition (existing and emerging)?

As You Start off on a License Negotiation…

- What and how much value does your IP bring to the business?
  - Materials,
  - Software
  - Know-how
- What kind of IP asset(s) do you have?
- How is the business going to be financed?
- Is it an existing licensee or a new venture?

What's the Single Most Important Factor that Determines the Value of Your IP?

- The name of the licensee!
  - Are they committed?
  - Capable?
  - Adequately resourced?

Valuation ➔ Pricing

- Various techniques
- Different answers
- An opinion

- A negotiation
- One outcome
- A commitment

Valuation ➔ Pricing

- With a valuation basis
- You negotiate the bases

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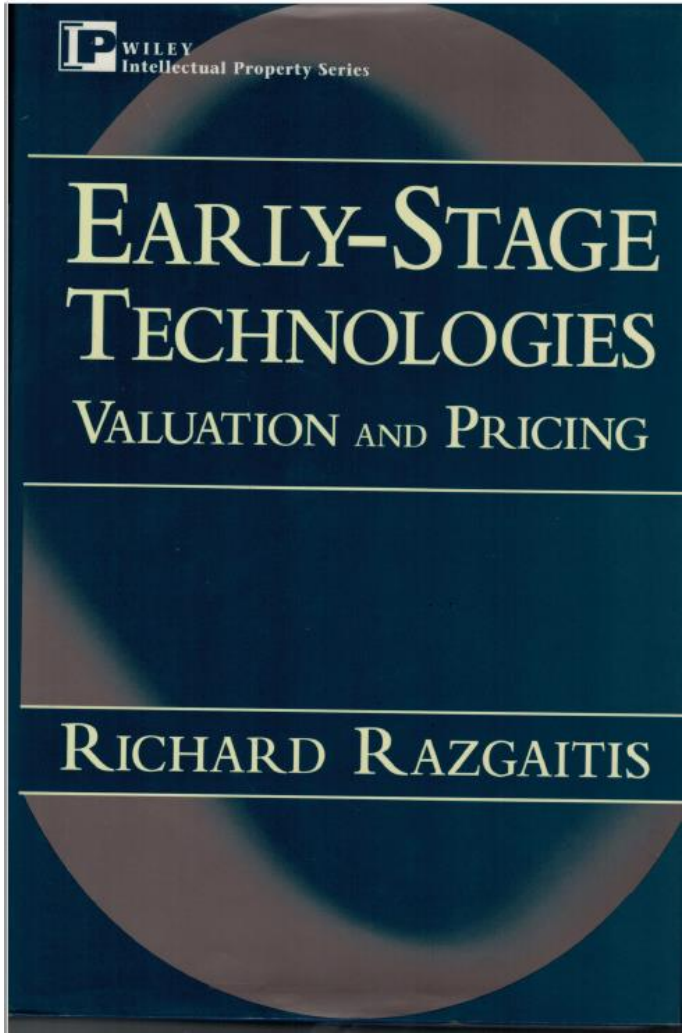
Valuation ➔ Pricing

- With a valuation basis
- Without a valuation basis

- You negotiate the bases
- You negotiate from emotion

When Is Technology Valued?

- Retrospectively
  - By litigators
  - Discovery to obtain all relevant information
  - Value established at a point in time
  - Adversarial -- outcome imposed judicially
- Prospectively
  - By deal makers
  - Asymmetry of information
    - University understands technology
    - Company knows the market
  - Value extracted over time
  - Must be win-win



First Edition -- 1999

What Do we Mean by a "Valuation"

- A written analysis of what we believe the value of a technology to be
- Prepared to:
  - Give it to the other side
  - Identify the sources of the data
  - Discuss the data
  - Modify based on discussions with the other side
    - Data
    - Valuation methodology used

What Do we Mean by a "License Valuation"

- Constructing the various financial elements of a proposed license
  - Upfront payments
  - Ongoing pre-commercial payments
    - Patent costs
    - Milestone payments
    - Annual Minimum Royalties
    - Research support
  - Sublicense income sharing
  - Earned royalties or sales/profit sharing
- **i.e., the Term Sheet**

Risk

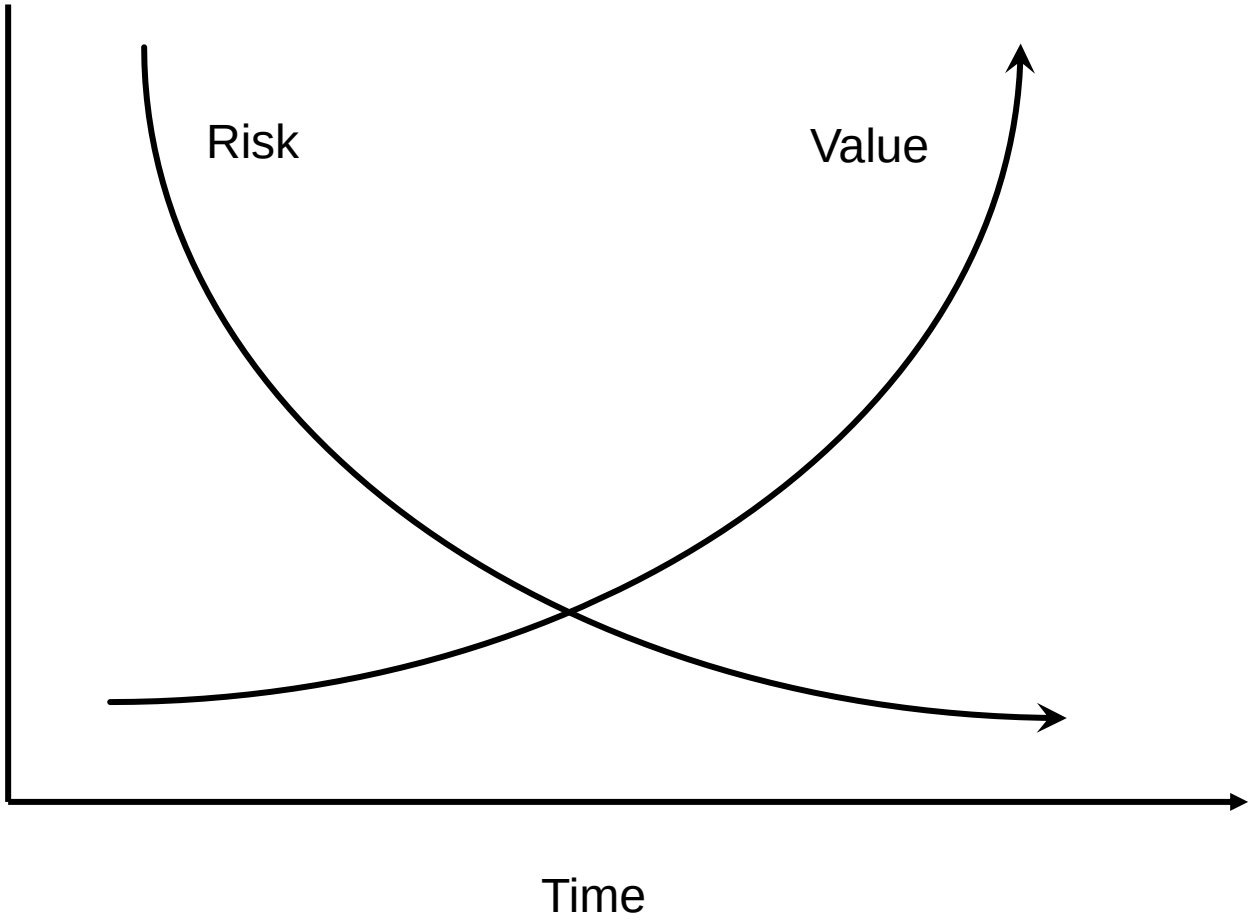
Types of Risk

- R&D risk
  - FDA risk
- Standards risk
- Manufacturability risk
- Marketing risk
- Competitive risk
- Legal risk
  - Patent risk

<u>Overall</u>

- I in 10,000 drug candidates makes it to FDA approval
- 1 in 3,000 raw ideas make it to market
- 1/3rd to 2/3rd of new product launches fail to recoup their investment

Value vs. Risk



A Fundamental Principle of License Valuation

- We probably shouldn't even **TRY** to get paid upfront in full
- Our job is to **EXTRACT** the value over time
  - Share in the growth in value

Example: Gatorade

- In 1963, Robert Cade of U. FL offered Stokely van Camp the rights* for $1 million
- Stokely van Camp declined
  - Said the test market would cost $1 million, paying Cade $1 million would double their financial risk
  - Offered to pay royalties
- To date, Stokely / Quaker / Pepsi have paid over $1 billion

* Rights consisted of patent applications, trade secret formula and **trademark**

Where is Value Extracted in a License?

- Upfront fee
- Ongoing pre-commercial payments
  - Patent costs
  - Milestone payments
  - Annual Minimum Royalties
- Research collaboration and support
- Sublicense income sharing
- Earned royalties

Royalty Payments

- Three basic types of payment:
  - Fixed lump sum payments
    - Single payments we get as long as the license is in effect
      - Upfront fee, annual maintenance fee, annual minimum royalties
  - Contingent lump sum payments
    - Single payments we get if certain things happen
      - Patent milestones, development milestones, sales milestones, equity liquidation, sublicense payments
  - Share the **increase in value** of the technology as it's developed
  - Running royalties
    - Payments that depend on the **extent** of licensee's use of the licensed technology
- Some payments are made pre-commercialization, some after

Upfront Payments

- Cash fee
  - Includes sunk patent costs
  - Reflects the initial value of the technology being transferred
    - Typically relatively low for academic technologies
  - A NewCo may only be able to pay in stock

Ongoing Pre-Commercial Payments

- Patent costs
- Milestone payments
  - Reflects increase in value of technology to licensee as they make progress
    - Common with life sciences inventions
    - Clinical development milestones
    - Patent milestones
    - Sales milestones
- Annual Minimum Royalties
  - Due diligence mechanism
    - Typically escalate substantially after 3 or so years
  - More common with physical sciences inventions

Sublicense Income Sharing

- Really important – with a start-up, this may be where the real value is created
- Challenge is that this is being negotiated years before the sublicense happens
  - Parties don't know how the sublicense will be structured
- University's objective will be to ensure that the licensee can't game the system by structuring the sublicense to minimize what it pays the university
  - Solution: University gets a piece of every payment that the licensee gets from the sublicensee

    You will pay me every which way there is

    Louis P. Berneman
- Exclusions for items for which there is a deliverable, and are documented in itemized accounts:
  - Research support payments
  - Purchases of equity

Sublicense Income Sharing

- Three models:
  1. Pass Through
     - University gets same running royalty on sublicensee's sales, as if the licensee sold the product; plus
     - A set percentage of every payment received other than running royalties (sometimes termed "non-royalty income")
  2. Allocation
     - University gets a set % of every payment the licensee gets from the sublicensee
       - Including running royalties
  3. Tiered Allocation
     - University gets a lower % of payments received from sublicensee, before commercialization
     - University gets a higher % of running royalties after commercialization
- Percentages may be based on timing of sub-licensing after license execution (e.g. year 1-25%, year 2-20%, year 3-15%)
  - Or stage of clinical development (i.e., licensee investment)

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Running Royalties

- Aka “Earned Royalties”
- The main post-commercialization economic component of the license
  - Biggest long term impact if the product is successful
- An equation:

  Royalty payments = Royalty base * Royalty rate
  - Payments are made for the Royalty Term

Royalty Base

- Measure of the **extent** of licensee's return from using the technology
  - Number of units sold
  - Sales
  - Profits
    - Define very, very carefully
      - Gross Profits / Net Profits / Profits after taxes
    - Very difficult (and expensive!) to audit
- Most common is "Net Sales"
    - Gross Sales less either
      - Standard deductions
        - Shipping / Insurance / Returns
      - Or a standard deduction – typically 2% or 3%

Royalty Rate

- **How much** of the licensee's return from using the technology we get
- Royalty rate can be either:
  - Flat
    - Single royalty rate for all sales
  - Tiered
    - Royalty rate is different at different levels of sales
    - Basic marketing theory says that bigger selling products are more profitable
      - Basic royalty theory (25% Rule) says royalty rate should therefore increase at higher sales levels

Royalty Term

- How long we get paid
- Universities usually use:
  - Last to expire patent on a country-by-country basis
- Companies frequently use:
  - Longer of:
    - Last to expire patent; and
    - Expiration of regularity exclusivity; and
    - Ten years from first commercial sale
      - Or more
        - Negotiate!
        - 12-15

    on a country-by-country basis

Royalty Term

- Why don't more universities use this formulation?
  - Need a royalty step down after patents expire
    - Kimble decision (2015) reaffirming Brulotte (1964)
  - 50% traditional
  - 10-25% meets the test
- Currently working on a case where CoM patent filed in 1970's
  - New use discovered in 1990's
  - FDA approval received 2019
    - Poorly worded
    - We'll see what the Court decides
- I see corporate licenses with no step down
  - Unenforceable in Court
    - But done

Royalty Term

- Reach through example:
  - License to novel protein and its gene
    - Licensed Patents
      - Normal definition
    - Other Patents
      - Inventions that could not have been made but for the use of the Licensed Technology
    - Potential products:
      - Protein as a biological therapeutic
        - Licensed Products
          - Protein therapeutic royalty rate, 4-6%
      - Protein as a screening target for small molecules
        - Other Products
          - Screening royalty rate, 0.5-1.0%
      - Get an either / or on Licensed Products and Other Products
        - One university did either / or on Other Patents / Products

A Problematic Issue – Combination Products

- An invoiced product that contains several components that could be considered separate products.
  - Your technology is only in one of the components
  - These separate parts may or may not be sold separately.

Combination Products – Example

- Vaccine for **Math Disease** and Spelling Disease sold together for $1,000
- Vaccine for Math Disease sold for $900 alone
  - Cost of goods sold is $50
- Vaccine for Spelling Disease sold for $300 alone
  - Cost of goods sold is $100
- Royalty Rate for Math Disease vaccine is 10%
  - Spelling Disease is not covered by our patents
    - Not royalty bearing

Combination Products – Example

- What is the Royalty Due?
  a. $90
  b. $75
  c. $50
  d. $33
- Normal solution is to prorate over the combined sales price
  - Math + Spelling = $1,200
    - Math is 75% of combined total
      - Royalty = 75% * $1,000 * 10%
        - $75

Combination Products – Example

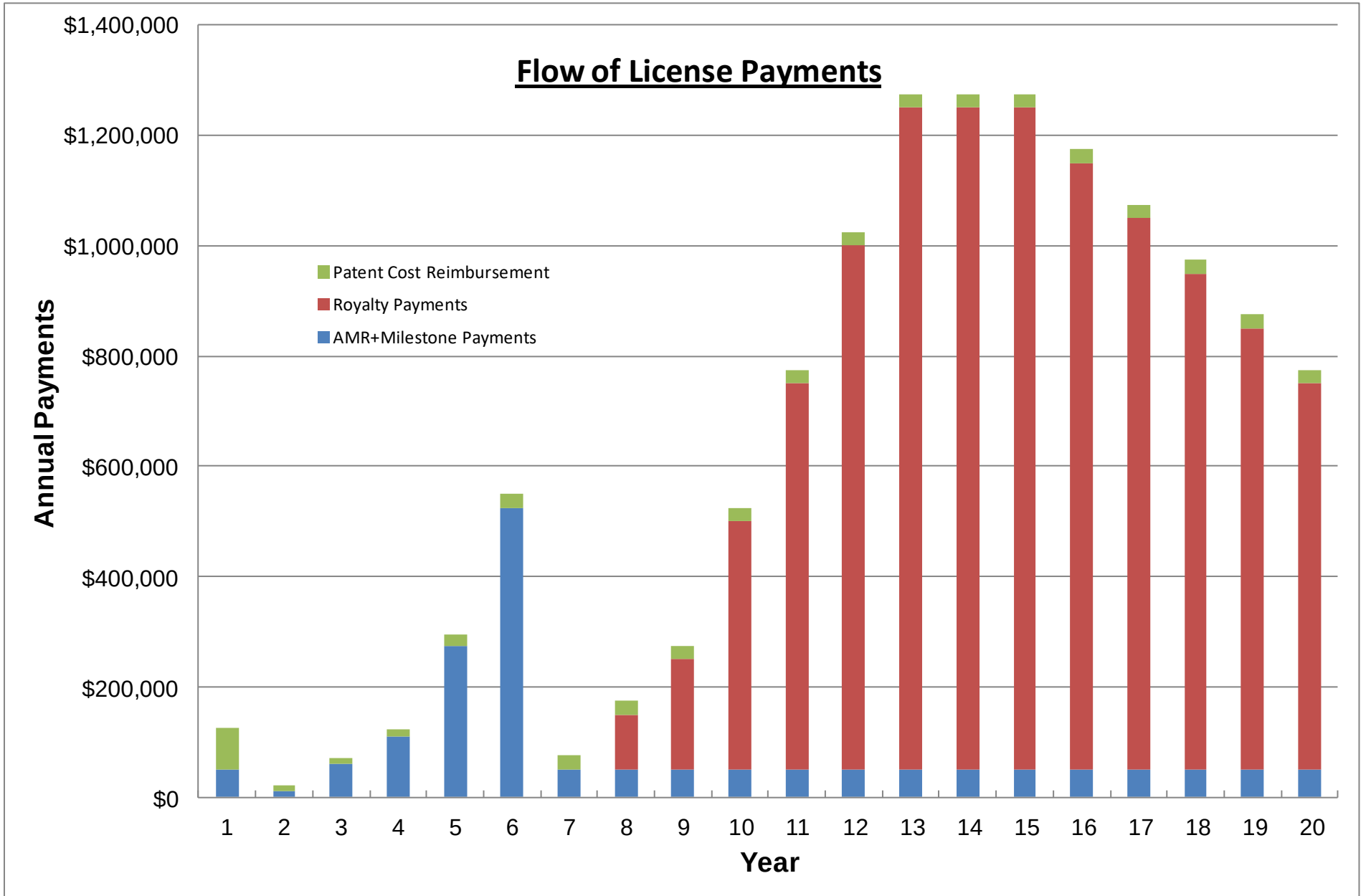
- Issue arises if one component is not sold separately
  - Historically, licenses often defaulted to prorating over CoGS
    - A terrible way
    - In our example, total CoGS = $150
      - Math is 33% of total
        - Royalty would be 33% * $1,000 * 10%
          - $33
  - I was unable to find an economically rational approach
    - "…..shall be determined in good faith….."
      - There is no good faith when there's money on the table
        - You'll finish up in arbitration
    - May just need to allocate equal value to each component

Example

License issue fee	$50k
Annual minimum royalties	$10k yrs 2-4 $25k yrs 5-7 $50k thereafter
Milestone payments	$50k yr 3 $100k yr 4 $250k yr 5 $500k yr 6
Royalty rate	5%
Sunk patent costs	$75k
Annual patent costs	$10 - $25k

Product Sales

Year	Product Sales
7	$750,000
8	$3,000,000
9	$5,000,000
10	$10,000,000
11	$15,000,000
12	$20,000,000
13	$25,000,000
14	$25,000,000
15	$25,000,000
16	$23,000,000
17	$21,000,000
18	$19,000,000
19	$17,000,000
20	$15,000,000


Flow of License Payments
$1,400,000
$1,200,000
$1,000,000
$800,000
$600,000
$400,000
$200,000
$0
Annual Payments
Patent Cost Reimbursement
Royalty Payments
AMR+Milestone Payments
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
Year

The Basic Ways to Approach Valuation -- the Licensing Guy's Perspective

- Cost
- Rules of Thumb
- Industry Standards – Comparables
- Ranking/Rating
- Discounted Cash Flow
- Monte Carlo
- Auction
- Common sense
- Equity

Today

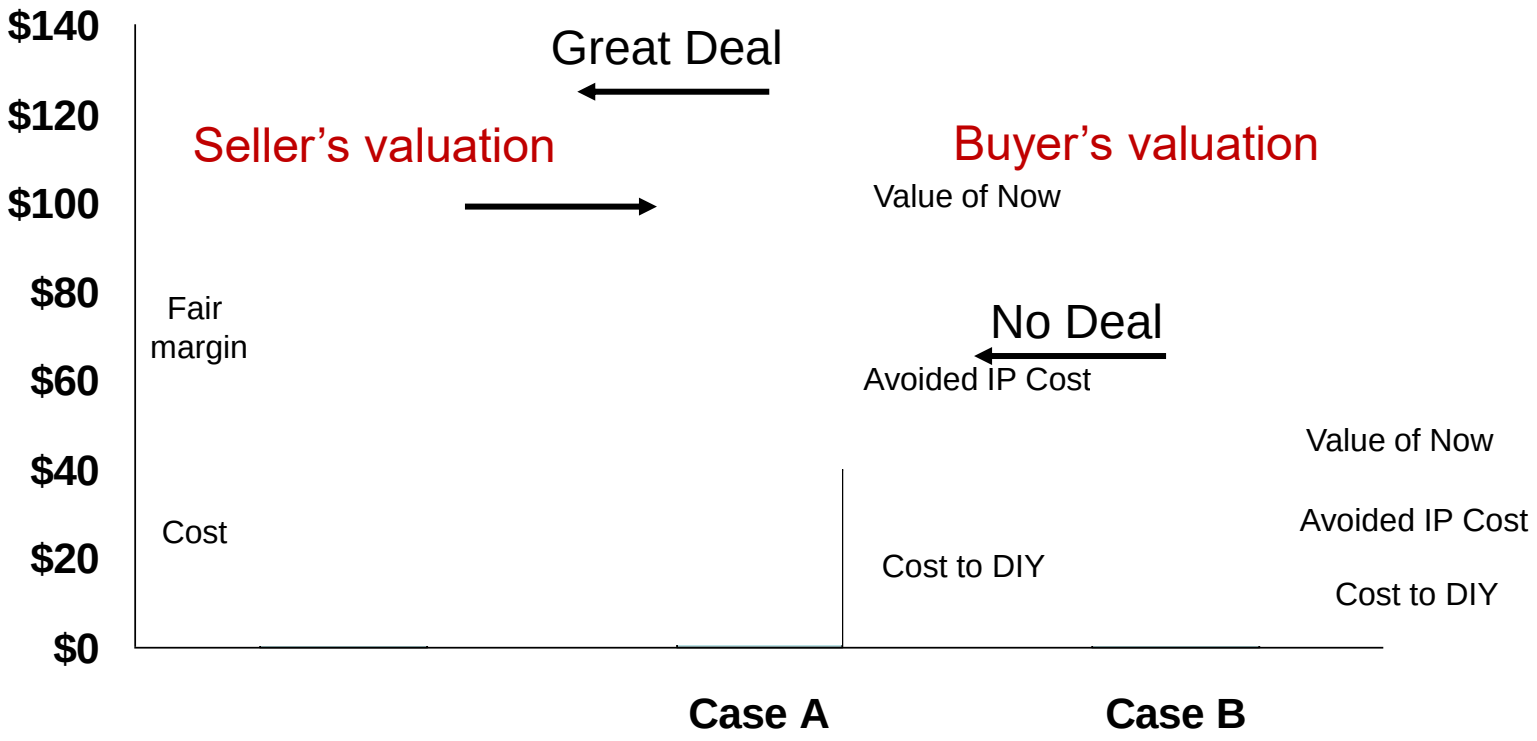
- Cost
- Rules of Thumb
- Industry Standards – Comparables
- Discounted Cash Flow

Look Back -- Cost

Look Back -- Cost

- Cost to develop plus a return
- Is cost to develop relevant?
  - Would you want to or be able to sell a used lottery ticket for what you paid for it?
  - Wasn't the technology developed with a GRANT?
- Two areas where cost enters in academic license negotiations:
  - Sunk patent costs
  - Relative ownership in a collaboration

Cost Driven Negotiation



Source: Richard Razgaitis

Examples of Cost-Based Valuations

- U. of Minnesota and Penn State sponsored research models
  - Sponsor can get a fully paid up license for an extra 10% of the research costs
    - 10% of the **fully loaded** costs, including IDC
- Disease foundation funding model
  - Demand royalties in return for their funding
    - Royalties typically capped at 2-3x amount invested

Look to your Hand – Rules of Thumb

-- the 25% Rule

A Fundamental Principle of Technology Valuation

The Goldscheider Principle

(aka the 25% Rule)

"The Licensor should receive 25% and the Licensee should receive 75% of the pre-tax profits from a licensed product"

The 25% Rule

- Based on empirical observations
  - 18 worldwide licenses by Swiss subsidiary of US TV company PhilCo starting in 1959
  - Complete IP portfolio - patents, ongoing know-how, trademarks, copyrighted product materials
  - Licensees made ~20% pre-tax profit, paid 5% royalty; were either #1 or #2 in their market despite strong competition
    - 3 year term, so readily renegotiable if terms inappropriate
    - Happily renewed the licenses
  - Concluded that the licenses resulted in successful, long term win-win relationships
- Applied to fully-loaded pre-tax profits, not gross margin

Application

- Expressed as a % of net sales in license

  Royalty rate = 25% x expected profit margin
- Starting point for negotiation
- Limited value in academic licensing negotiations because of early stage
  - Very helpful when you're licensing to a new industry

Look Around – Industry Standards/Comparables

Comparable Transactions

- Probably the most important valuation method for academic licensing.
- Sources of Comparable Transactions
  - Internal database
  - Published surveys
  - Public announcements
  - Word of mouth
  - Litigation
  - Required disclosure

Internal Database

- Licenses previously done by your organization
- Trends over time

Published Surveys

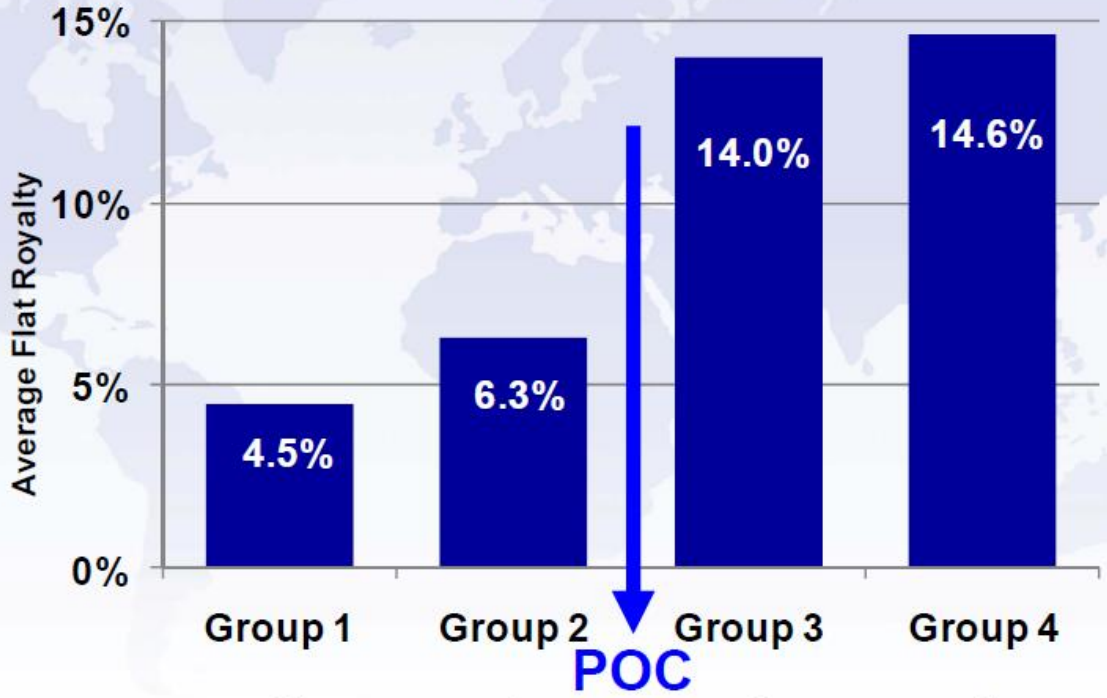
- Relatively few in number
- Most are really old
- Three good current surveys:
  - LES
    - BioPharmaceutical Royalty Rates and Deal Terms Survey (2008, 2009, 2012, 2014, 2016, 2018, 2021)
    - High Tech Survey (2011, 2014, 2017, 2021)
    - Chemicals, Energy, Environmental and Materials (CEEM) Survey (2010)

LES BioPharmaceutical Royalty Rates and Deal Terms Survey – 2016

- 165 responses, 117 complete and used
- Oncology, CNS and infectious diseases most prevalent
- 84% were exclusive
- 87% included U.S. and 80% were global
- 55% pre-IND
  - Very useful for universities
- 68% had expected peak sales <$500 million
- Royalty structure
  - 62% fixed royalties
  - 27% tiered royalties
  - 9% no royalty
    - 1% profit share
    - 8% no royalties

Flat Royalties
Average Royalty by Stage of Development

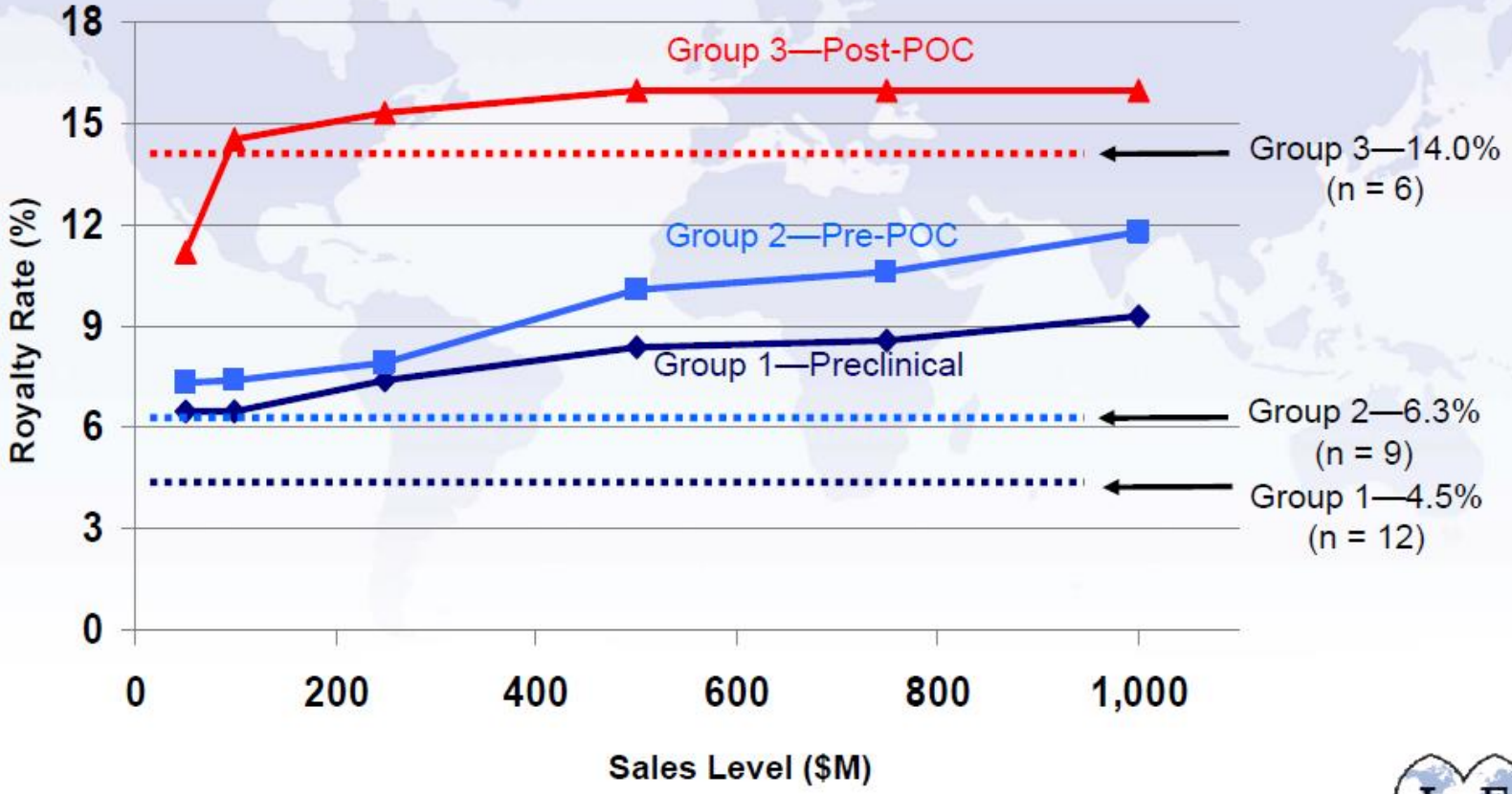
Royalty level increased with stage of development.



	Group 1	Group 2	Group 3	Group 4
No. of deals	27	6	5	7
Median	5%	5%	16%	15%
Min	1%	2%	3%	7%
Max	10%	20%	20%	30%

Flat vs. Tiered Royalties
Stage of Development

Within groups, mean flat royalty levels were below the values for tiered royalties.



AUTM

- TransACT
- Launched 2015
  - Academic deals
    - “Display or Pay”
      - Contribute a number of deals depending on your research volume
- Has severe limitations
  - The subject matter must be selected from a pick-list
    - All healthcare is the same code
      - E.g., a search for small molecule drugs yields ~80 hits
        - 26 have royalty rates
  - Can’t download all the data into a spreadsheet for analysis
    - One by one
- May be most useful for non-healthcare

Required Disclosure

- Contained in SEC filings
- Company must be public or have filed to go public
- Contained in **exhibits** to the S1 (IPO), 10K (Annual Report), 10Q (Quarterly Report) or 8K (Material Event)
- Only for “Material” transactions
  - 10% of sales, or
  - 5% of assets
- Can redact commercially sensitive information from public disclosure
  - Redaction has increased since transition to electronic filing
  - Redaction only good for 5 years
    - Some databases good at going back and getting the unredacted data

Steps

- Identify comparable transactions that would be helpful models
- Determine if the agreement has been filed with SEC
- Find it!

Accessing SEC Filings Yourself

- SEC EDGAR system
  - www.sec.gov/edgar/searchedgar/companysearch.html
  - Getting a lot more user friendly
  - Companies phased in progressively:
    - Largest January 1994
    - Smallest May 1996
  - For pre-Edgar transactions, early10K will show when/whether it was filed

Some Databases to Find Comparables

Technology	
RoyaltySource	royaltysource.com/
RoyaltyStat	www.royaltystat.com/
Business Valuation Resources	www.bvresources.com/

Life Sciences	
Clarivate (former ReCap)	www.cortellis.com/intelligence
BioScience Advisors	www.biosciadvisors.com
IQVIA (former PharmaDeals)	www.pharmadeals.net/
Strategic Transactions (Windhover)	www.elsevierbi.com/deals

- All charge – either per agreement ($35) or an annual subscription
- Some let you identify agreements before you have to pay
  - Find them yourself through the SEC

Search Strategies

- No Cost
  - Search using Strategic Transactions (Life Sciences)
    - Physical sciences one has gone out of business
  - Find agreements using SEC
- High Cost Life Sciences
  - Search and get agreements using Clarivate or BioScience Advisors
- Alternative
  - Use a consultant for a specific technology
  - $2-3,000

Example

- siRNA
- Tools:
  - Clarivate
  - EDGAR

Cortellis

Clarivate Analytics

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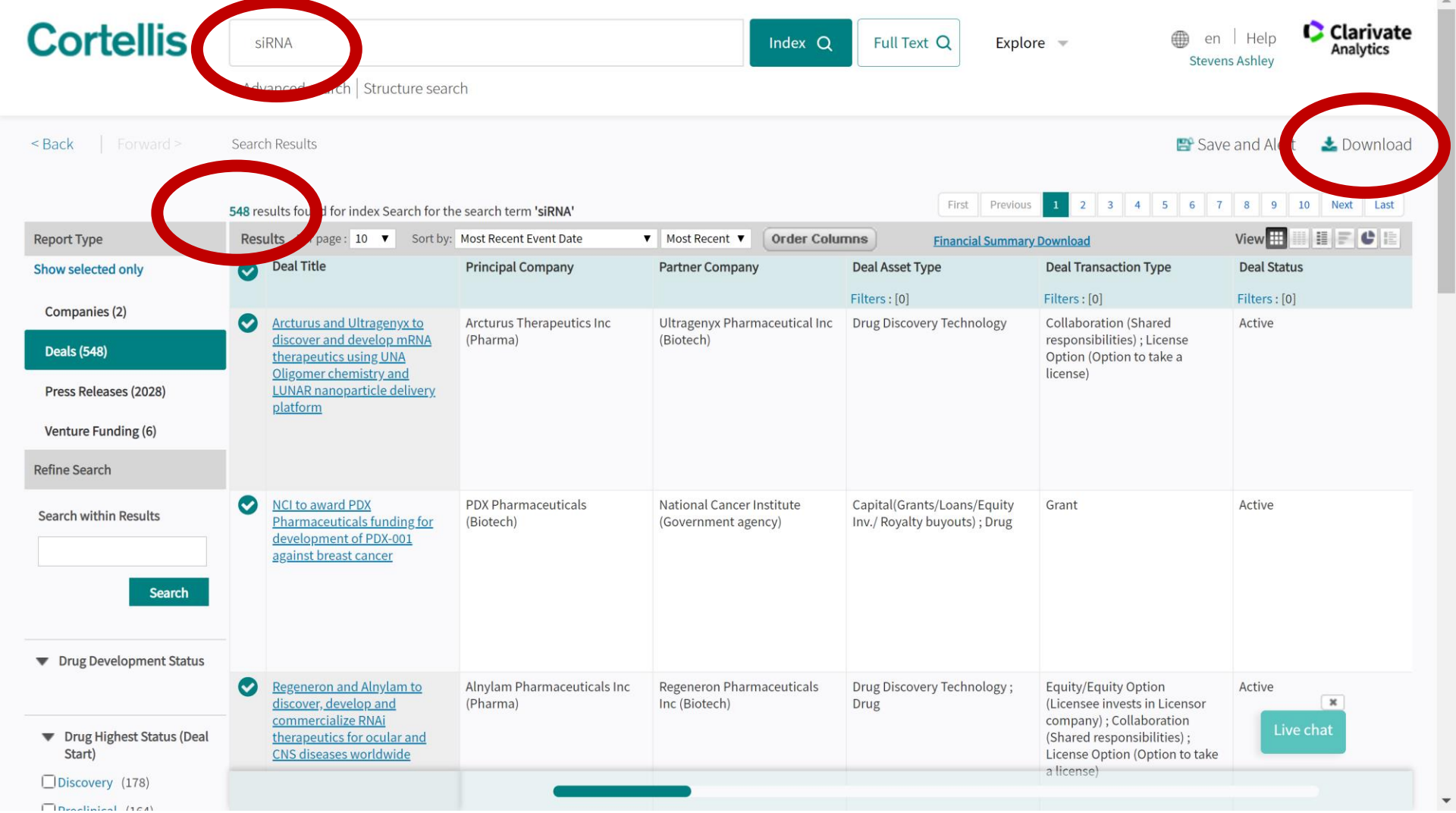


Deal Title	Principal Company	Principal Company Typ
Arcturus and Ultragenyx to discover and develop mRNA therapeutics using UNA	Arcturus Therapeutics Inc	Pharma
NCI to award PDX Pharmaceuticals funding for development of PDX-001 against breast	PDX Pharmaceuticals	Biotech
Regeneron and Alnylam to discover, develop and commercialize RNAi therapeutics for	Alnylam Pharmaceuticals Inc	Pharma
Janssen to develop and commercialize Arrowhead's ARO-HBV, with an option to	Arrowhead Pharmaceuticals Inc	Pharma
Nitto Denko and Osaka International Cancer Institute to develop new nucleic acid	Nitto Denko Corp	Other (non industrial)
Genzyme to develop Alnylam's RNAi therapeutics worldwide, excluding North	Alnylam Pharmaceuticals Inc	Pharma
Thea to develop and commercialize OliX's OLX-301A against age-related macular	OliX Pharmaceuticals Inc	Pharma
Karolinska Institute to conduct clinical trial for Alnylam Pharmaceuticals' givosiran for acute	Karolinska Institutet	Academic
Medison Pharma to commercialize Alnylam's RNAi therapeutics for rare diseases in Israel	Alnylam Pharmaceuticals Inc	Pharma
Covance to provide OliX with GLP toxicology study services for OLX-10020 against GA	Covance Inc	Biotech
OliX Pharmaceuticals and University of Virginia School of Medicine to conduct	University of Virginia School of Medicine	Academic
Dicerna and Boehringer to discover and develop GalXC RNAi therapeutics for NASH	Dicerna Pharmaceuticals Inc	Pharma
Aro Biotherapeutics to develop and commercialize Janssen's Centyrin protein	Janssen Pharmaceuticals Inc	Pharma

Results

- 36 fields, covering:
  - Partners
  - Technology
  - Legal components of the deal
  - Financial terms
  - Actual documents
  - Stage of development

Results

- 548 deals
  - 109 had some financial information
  - 25 had royalty information
- 164 PSRI
  - 122 academic
  - 13 government agency
  - 29 non-profit
    - 41 had some financial information
    - 6 had royalty information, 1% - 10%
    - 6 had license agreement
      - 4 unredacted
      - 2 redacted

Results

Principal Company	Partner Company	Therapy Area	Indications	Drugs Status	Date	Total Value	Upfr.	Milest.	Royalty Rate (%)
Mayo Clinic	Alnylam	CNS	Parkinsons	Preclinical	10/01/03	3.97		3.75	1.00
Stanford	Alnylam	Unknown	Unidentified	Preclinical	09/17/03	0.77		0.73	2.00
U. of Penns.	Acuity	Ocular	AMD	Preclinical	03/31/03	1.00		0.95	2.00
U. of Illinois	Acuity	Ocular	Ocular	Discovery	08/01/06	2.50	0.03	2.45	3.00
UMass Med. Sch.	CytRx	Var,	Onc., NIDDM; Obesity	Discovery	04/15/03	6.50	0.08	6.3	10.00
UMass Med. Sch.	CytRx	CNS	ALS	Discovery	04/15/03	34.13	0.01	1.57	10.00

Old System

- A lot has been lost as the ReCap database has been repeatedly sold and reformatted
  - The unredacted copy of the agreement is available
    - Was in ReCap and Thomson Reuters versions
  - Only redacted version of the Acuity-U. of IL deal is available in Clarivate
  - Following is from the Thomson Reuters days
- I've changed my subscription to the new database created by Mark Edwards, BioScience Advisors
  - Creator of ReCap

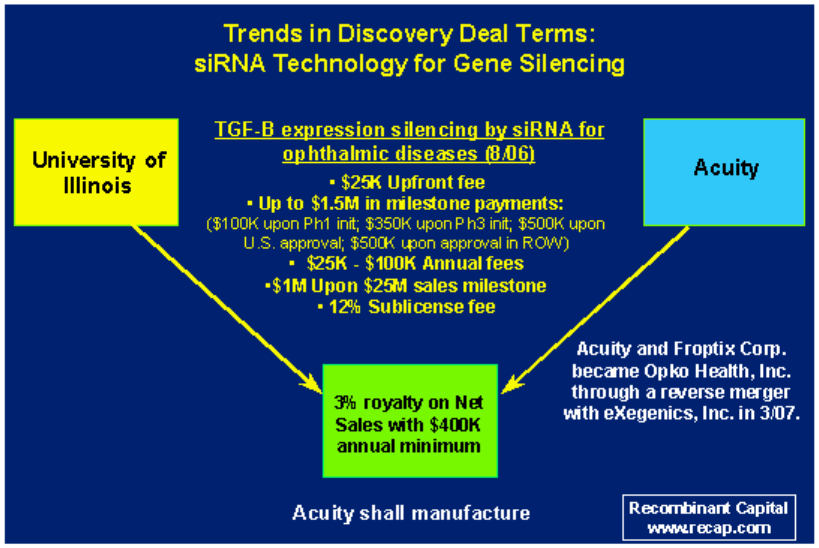
Alliance Summary

R&D Company:	University of Illinois	**R&D Parent:**	
Client Company:	Acuity Pharmaceuticals	**Client Parent:**	Opko Health

Date: 08/2006
Parties: University / Biotech
Type: License
Subject:
TGF-B expression silencing by siRNA for ophthalmic diseases

Size:	$ 2.5 M	**Therapeutic Area:**	Ophthalmic Broad Focus Ophthalmic
Equity:	$ 0 M	**Technology:**	Gene Expression, Oligonucleotides - Ribozymes
Max. Royalty:	3 %	**Stage (at signing):**	Discovery

SNAPSHOT:



LICENSE

Contract Analysis

R&D Company:	University of Illinois	**R&D Parent:**	
Client Company:	Acuity Pharmaceuticals	**Client Parent:**	Opko Health
Agreement Date:	08/2006		
Alliance Summary:	Open parent Alliance Summary		

Related Contracts:

Agreement	Contract type	Contract date	pdf	Refile
University of Illinois / Acuity Pharmaceuticals (08/2006)	License	08/2006		

I. Research & Development

A. Scope of the Agreement
On 8/3/2006 ("Effective Date"), the University of Illinois (the "University") and Acuity Pharmaceuticals, Inc. ("Acuity") entered into a license agreement ("Agreement") to develop treatments for ophthalmic diseases based on TGF-beta receptor expression silencing by siRNA. [On 3/27/2007, Acuity and Froptix Corporation ("Froptix"), both privately owned, became Opko Health, Inc. ("Opko") through a reverse merger with publicly-traded eXegenics, Inc. (see Separate Deal Background -- Opko / Acuity, Froptix 3/07).]

B. Research Period
N/A

C. Cost Sharing & Reimbursement Basis
N/A

D. Upfront Payment
Acuity shall pay the University a $25K license fee within 3 business days of the Effective Date.

E. Benchmark Amounts
Acuity shall pay the University the following one-time milestone payments upon the first achievement of the following development milestone events: (1) $100K upon the initiation of phase I; (2) $350K upon the initiation of phase III; (3) $500K upon approval in the U.S.; and (4) $500K upon approval outside the U.S. Acuity shall pay the University a sales milestone of $1M upon reaching the first $25M in commercial sales of the Licensed Product (see Section II.A.).

F. Technology Acquisition Fees
N/A

G. Payment Schedule
N/A

H. Budgets
No

I. Reimbursement Start Date:
N/A

J. Regulatory Filings
All by Acuity.

K. Special Capital Requirements
None

L. Patent Ownership
The University shall not be obliged to provide Acuity or its sublicensees with any updates to the Technical Information. "Technology" shall mean the Inventions, Licensed Patents, and Technical Information, collectively. "Inventions" shall mean all devices, machines, methods, processes, manufactures, compositions of matter and uses, and Technical Information, contained in the disclosure entitled "CW081 Silencing of TGF-beta Receptor Expression by siRNA." "Licensed Patents" shall mean the following patents and applications owned by the University including any continuations, reissues, or foreign

Contract

R&D:	University of Illinois	**R&D Parent:**	
Client:	Acuity Pharmaceuticals	**Client Parent:**	Opko Health
Parties:	University / Biotech	**Subject:**	TGF-B expression silencing by siRNA for ophthalmic diseases
Alliance Summary:	Open parent Alliance Summary		

Alliance Type:	License	**Date:**	08/2006
		Revision:	

Contract Type:	License	**Filing Date:**	08/2006

CONTENT: EX-10.8 8 g06337exv10w8.htm EX-10.8 TECHNOLOGY LICENSE AGREEMENT

EXHIBIT 10.8

TECHNOLOGY LICENSE AGREEMENT

License Agreement ("**Agreement**"), effective as of August 3, 2006 between THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS, (the "**University**"), and ACUITY PHARMACEUTICALS, INC., a Delaware corporation, having its principle place of business at 3701 Market Street, Philadelphia, PA, 19104 ("**Licensee**" or "**Acuity**").

Preliminary Statement

University holds certain rights to the Technology described below and desires to have the Technology commercialized. Licensee wishes to obtain the right to use the Technology for commercial purposes. Therefore, in consideration of the mutual obligations set forth below and other valuable consideration, the receipt and sufficiency of which is hereby acknowledged, University and Licensee agree as follows.

ARTICLE I
DEFINITIONS

The following capitalized terms are used in this Agreement with the following meanings:

1.1. "**Effective Date**" means August 3, 2006.

1.2. **"FDA"** means the United States Food and Drug Administration, or any successor thereto.

1.3. "**IND**" means an "investigational new drug application" as defined by the United States Food, Drug, and Cosmetic Act, as amended (the "Act"), and applicable FDA rules and regulations or a foreign equivalent.

1.4. **"Inventions"** means all devices, machines, methods, processes, manufactures, compositions of matter and uses, and Technical Information, contained in the disclosure entitled "CW081 Silencing of TGF ß Receptor Expression by SiRNA."

1.5. "**Licensed Field**" means the inhibition of and treatment of ophthalmic disease.

1.6. "**Licensed Patents**" means (a) the patents and patent applications listed on Schedule 1 and any continuations, divisionals, reissues, renewals, re-examinations, foreign counterparts, or substitutions of or to the above.

1.7. "**Licensed Product**" means any product or process or license for information, in the Field of Use, that is distributed by Licensee that is covered by any of the University's rights in the Technology.

1.8. **"NDA"** means a "new drug application," as defined in the Act and applicable FDA rules and regulations, including an application of the type described in section 505(b)(2) of the Act.

obligation to provide Licensee or any Sublicensee with any updates of or additional Technical Information owned, controlled or in the possession of any of them.

ARTICLE III
PAYMENTS

3.1. **Royalties and Reimbursements**. For the licenses granted in Section 2.1 of this Agreement, Licensee shall:

(a) within three (3) business days of the execution of this Agreement, pay University a non-refundable licensing fee in the amount of $25,000;

(b) within thirty (30) days of the first and second anniversary of the Effective Date, pay University a non-refundable licensing fee in the amount of $25,000;

(c) within thirty (30) days of the third anniversary of the Effective Date, pay University a non-refundable licensing fee in the amount of $50,000;

(d) within thirty (30) days of the fourth anniversary of the Effective Date, pay University a non-refundable licensing fee in the amount of $50,000;

(e) within thirty (30) days of the fifth anniversary of the Effective Date and each subsequent anniversary thereafter until the Licensee receives NDA approval on its first Licensed Product, pay University an annual non-refundable licensing fee in the amount of $100,000;

(f) pay University a Royalty equal to three percent (3%) of Net Sales of Licensed Products sold, leased, rented, licensed or otherwise distributed by Licensee during the term of this Agreement, if any. If no valid claim of any issued patent among the Licensed Patents covers the Licensed Products in a country of the Territory, then the royalties shall be reduced to one and one-half percent (1.5%) of Net Sales of Licensed Products sold, leased, rented, licensed or otherwise distributed by Licensee in such country of the Territory.

3.2. **Milestones and Milestone Payments**. Licensee agrees to make the milestone payments to University as set forth below (the "**Milestone Payments**") within forty-five (45) days after the occurrence of each event set forth on such Schedule.

Milestone		**Payment**
First Phase I Clinical Trial initiated	$	100,000
First Phase III Clinical Trial initiated	$	350,000
First NDA Approval in the U.S	$	500,000
First NDA Equivalent Approval outside of US	$	500,000
Upon first $25,000,000 of commercial sales of any Licensed Products	$	1,000,000

Each of the foregoing payments shall be made only once. Thereafter, no additional Milestone Payments shall be due or payable by Licensee for License Products.

3.3. **Calculations and Payment of Royalties.**

(a) Royalties shall be paid in quarterly increments (the "Royalty Period"). Royalties shall be calculated for each Royalty Period as of the last day of each such Royalty Period. Payment of Royalties with respect to each Royalty Period shall be due within sixty (60) days after the end of Royalty Period, beginning with the earlier of (i) the Royalty Period in which the first sale of a Licensed Product occurs, or (ii) the Royalty Period for which Annual Minimum Royalties are due.

(b) Within sixty (60) days of the end of each Royalty Period (whether or not Royalties are due), Licensee shall deliver to University a true and complete accounting of sales or distributions of any Licensed Product and revenues from those sales by Licensee and its Sublicensees for each country of sales origin during such Royalty Period and deductions taken, with a separate accounting for each Licensed Product of sales and receipts by country, and a detailed calculation of the Royalty payment due University for such Royalty Period, in each case in form and

Search Results

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8 results.
CRITERIA: ([Company] CONTAINS "Acuity Pharmaceuticals")

	Parties	Date	Type	Size	Upfront	Total Milestone	Royalty	Subject
1	Acuity Pharmaceuticals, Froptix / Opko Health	03/2007	Acq, Mrg					Reverse merger with eXegenics to form Opko Health
2	University of Illinois / Acuity Pharmaceuticals	08/2006	L	$2.5	$0.0	$1.5	3.0%	TGF-B silencing by siRNA for ophthalmic diseases
3	ZaBeCor / Acuity Pharmaceuticals	04/2006	L, O					Excellair anti-Inflammatory siRNA for Ophthamalic uses
4	Pathogenics / Acuity Pharmaceuticals	04/2006	L	$6.5	$0.1	$6.4	6.0%	N-chlorotaurine For Ophthalmic Use
5	Intradigm / Acuity Pharmaceuticals	06/2005	CoD, Col, L, E	$5.6	$0.5	$5.1	8.0%	siRNA for topical delivery to the eye
6	Ocimum Biosolutions / Acuity Pharmaceuticals	08/2004	L					Genchek-Comprehensive Sequence Analysis Tool
7	University of Pennsylvania / Acuity Pharmaceuticals	03/2003	L, E	$1.0		$1.0	8.0%	RNA interference technologies (Gewirtz)
8	University of Pennsylvania / Acuity Pharmaceuticals	03/2003	L, E	$1.0		$1.0	2.0%	RNA interference technologies (Reich/Tolentinio)

U.S. SECURITIES AND EXCHANGE COMMISSION

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SIC: 2834 - PHARMACEUTICAL PREPARATIONS
State location: FL | State of Inc.: **DE** | Fiscal Year End: 1231
formerly: CYTOCLONAL PHARMACEUTICS INC /DE (filings through 2001-06-04)
formerly: EXEGENICS INC (filings through 2007-06-13)
formerly: eXegenics Inc (filings through 2007-06-13)
(Assistant Director Office: 1)
Get **insider transactions** for this **issuer**.
Get **insider transactions** for this **reporting owner**.

Business
4400 BISC
MIAMI FL
305-575-4

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Items 1 - 40 RSS Feed

Filings	Format	Description
8-K	Documents	Current report, item 5.02 Acc-no: 0000944809-19-000043 (34 Act) Size: 37 KB
8-K	Documents	Current report, items 5.03, 5.07, 7.01, and 9.01 Acc-no: 0000944809-19-000041 (34 Act) Size: 89 KB
SC 13D	Documents	General statement of acquisition of beneficial ownership Acc-no: 0001193125-19-171306 Size: 124 KB
SC 13D	Documents	General statement of acquisition of beneficial ownership Acc-no: 0001193125-19-171303 Size: 117 KB
SC 13D	Documents	General statement of acquisition of beneficial ownership Acc-no: 0001193125-19-171298 Size: 113 KB
SC 13D	Documents	General statement of acquisition of beneficial ownership Acc-no: 0001193125-19-171297 Size: 116 KB
8-K	Documents	Current report, item 7.01 Acc-no: 0000944809-19-000039 (34 Act) Size: 30 KB
8-K	Documents	Current report, item 8.01 Acc-no: 0000944809-19-000036 (34 Act) Size: 28 KB

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formerly: eXegenics Inc (filings through 2007-06-13)
(Assistant Director Office: 1)
Get **insider transactions** for this **issuer**.
Get **insider transactions** for this **reporting owner**.

Business Address
4400 BISCAYNE BLVD.
MIAMI FL 33137
305-575-4138

Ma
44
MI

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Items 1 - 40 RSS Feed

Filings	Format	Description	Filing Date
8-K	Documents	Current report, items 1.01, 3.02, and 9.01 Acc-no: 0001144204-07-065847 (34 Act) Size: 52 KB	2007-12-05
8-K	Documents	Current report, items 1.01, 2.01, and 9.01 Acc-no: 0001144204-07-064922 (34 Act) Size: 49 KB	2007-11-29
8-K	Documents	Current report, items 5.02 and 8.01 Acc-no: 0000950144-07-008821 (34 Act) Size: 12 KB	2007-09-25
8-K	Documents	Current report, items 1.01, 5.02, and 9.01 Acc-no: 0000950144-07-004724 (34 Act) Size: 66 KB	2007-05-11
8-K	Documents	Current report, item 1.01 Acc-no: 0000950144-07-003524 (34 Act) Size: 11 KB	2007-04-18
8-K	Documents	Current report, items 4.01, 5.02, and 9.01 Acc-no: 0000950144-07-003401 (34 Act) Size: 47 KB	2007-04-13
8-K	Documents	Current report, items 1.01, 2.01, 3.02, 5.01, 5.02, 5.06, and 9.01 Acc-no: 0000950144-07-002945 (34 Act) Size: 2 MB	2007-04-02
8-K	Documents	Current report, items 3.03 and 9.01 Acc-no: 0001144204-07-014826 (34 Act) Size: 44 KB	
8-K	Documents	Current report, items 3.02, 5.01, 5.02, 8.01, and 9.01	2007-02-09

Form 8-K - *Current report:*

Filing Date
2007-04-02
Accepted
2007-04-02 07:13:22
Documents
22

Period of Report
2007-03-27

Items
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Item 2.01: Completion of Acquisition or Disposition of Assets
Item 3.02: Unregistered Sales of Equity Securities
Item 5.01: Changes in Control of Registrant
Item 5.02: Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers: Compensatory Arrangements of Certain Officers
Item 5.06: Change in Shell Company Status
Item 9.01: Financial Statements and Exhibits

Document Format Files

Seq	Description	Document	Type	Size
1	EXEGENICS, INC.	g06337e8vk.htm	8-K	889948
2	EX-2.1 MERGER AGREEMENT & PLAN OF REORGANIZATION	g06337exv2w1.htm	EX-2.1	294509
3	EX-4.1 FORM OF COMMON STOCK WARRANT	g06337exv4w1.htm	EX-4.1	33331
4	EX-4.2 FORM OF SERIES C PREFERRED STOCK WARRANT	g06337exv4w2.htm	EX-4.2	32645
5	EX-10.1 FORM OF LOCK-UP AGREEMENT	g06337exv10w1.htm	EX-10.1	9947
6	EX-10.2 CREDIT AGREEMENT	g06337exv10w2.htm	EX-10.2	86185
7	EX-10.3 AMENDED & RESTATED VENTURE LOAN AGREEMENT	g06337exv10w3.htm	EX-10.3	210041
8	EX-10.8 TECHNOLOGY LICENSE AGREEMENT	g06337exv10w8.htm	EX-10.8	96413
9	EX-10.9 LICENSE AGREEMENT	g06337exv10w9.htm	EX-10.9	87487
10	EX-10.10 AMENDMENT NO. 1 TO LICENSE AGREEMENT	g06337exv10w10.htm	EX-10.10	8079
11	EX-10.11 AMENDMENT NO. 2 TO LICENSE AGREEMENT	g06337exv10w11.htm	EX-10.11	7548
12	EX-10.12 LICENSE AND COLLABORATION AGREEMENT	g06337exv10w12.htm	EX-10.12	127884
13	EX-10.13 UNIV. OF PENN. LICENSE AGREEMENT	g06337exv10w13.htm	EX-10.13	66692
14	EX-10.14 UNIV. OF PENN LICENSE AGREEMENT	g06337exv10w14.htm	EX-10.14	66493
15	EX-10.15 1ST AMENDMENT TO UPENN LICENSE AGREEMENT	g06337exv10w15.htm	EX-10.15	12050
16	EX-10.16 1ST AMENDMENT TO UPENN LICENSE AGREEMENT	g06337exv10w16.htm	EX-10.16	10147
17	EX-10.17 AMENDED RESTATED SUBORDINATION AGREEMENT	g06337exv10w17.htm	EX-10.17	25982
18	EX-10.18 REICH EMPLOYMENT LETTER	g06337exv10w18.htm	EX-10.18	25379
19	EX-10.19 PFOST EMPLOYMENT AGREEMENT	g06337exv10w19.htm	EX-10.19	51353
20	EX-99.1 PRESS RELEASE	g06337exv99w1.htm	EX-99.1	9676
21	GRAPHIC	g06337g0633701.gif	GRAPHIC	7428
22	GRAPHIC	g06337g0633702.gif	GRAPHIC	1541
	Complete submission text file	0000950144-07-002945.txt		216658

eXegenics Inc (Filer) CIK: 0000944809 (see all company filings)

IRS No.: **752402409** | State of Incorp.: **DE** | Fiscal Year End: **1231**
Type: **8-K** | Act: **34** | File No.: **000-26648** | Film No.: **07735592**

Business Address
1250 PITTSFORD-VICTOR ROAD
BUILDING 200, SUITE 280

EXHIBIT 10.8

TECHNOLOGY LICENSE AGREEMENT

License Agreement ("**Agreement**"), effective as of August 3, 2006 between THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS, (the "**University**"), and ACUITY PHARMACEUTICALS, INC., a Delaware corporation, having its principle place of business at 3701 Market Street, Philadelphia, PA, 19104 ("**Licensee**" or "**Acuity**").

Preliminary Statement

University holds certain rights to the Technology described below and desires to have the Technology commercialized. Licensee wishes to obtain the right to use the Technology for commercial purposes. Therefore, in consideration of the mutual obligations set forth below and other valuable consideration, the receipt and sufficiency of which is hereby acknowledged, University and Licensee agree as follows.

ARTICLE I
DEFINITIONS

The following capitalized terms are used in this Agreement with the following meanings:

1.1. "**Effective Date**" means August 3, 2006.

1.2. **"FDA"** means the United States Food and Drug Administration, or any successor thereto.

1.3. "**IND**" means an "investigational new drug application" as defined by the United States Food, Drug, and Cosmetic Act, as amended (the "Act"), and applicable FDA rules and regulations or a foreign equivalent.

1.4. **"Inventions"** means all devices, machines, methods, processes, manufactures, compositions of matter and uses, and Technical Information, contained in the disclosure entitled "CW081 Silencing of TGF ß Receptor Expression by SiRNA."

1.5. "**Licensed Field**" means the inhibition of and treatment of ophthalmic disease.

1.6. "**Licensed Patents**" means (a) the patents and patent applications listed on Schedule 1 and any continuations, divisionals, reissues, renewals, re-examinations, foreign counterparts, or substitutions of or to the above.

1.7. "**Licensed Product**" means any product or process or license for information, in the Field of Use, that is distributed by Licensee that is covered by any of the University's rights in the Technology.

1.8. **"NDA"** means a "new drug application," as defined in the Act and applicable FDA rules and regulations, including an application of the type described in section 505(b)(2) of the Act.

1.9. "**Net Sales**" means the total gross proceeds to Licensee on sales and any other distributions of Licensed Products to third parties, less deductions for the following to the extent actually paid with respect to such sales or distributions:

(a) Customary rebates;

3.1. **Royalties and Reimbursements**. For the licenses granted in Section 2.1 of this Agreement, Licensee shall:

(a) within three (3) business days of the execution of this Agreement, pay University a non-refundable licensing fee in the amount of $25,000;

(b) within thirty (30) days of the first and second anniversary of the Effective Date, pay University a non-refundable licensing fee in the amount of $25,000;

(c) within thirty (30) days of the third anniversary of the Effective Date, pay University a non-refundable licensing fee in the amount of $50,000;

(d) within thirty (30) days of the fourth anniversary of the Effective Date, pay University a non-refundable licensing fee in the amount of $50,000;

(e) within thirty (30) days of the fifth anniversary of the Effective Date and each subsequent anniversary thereafter until the Licensee receives NDA approval on its first Licensed Product, pay University an annual non-refundable licensing fee in the amount of $100,000;

(f) pay University a Royalty equal to three percent (3%) of Net Sales of Licensed Products sold, leased, rented, licensed or otherwise distributed by Licensee during the term of this Agreement, if any. If no valid claim of any issued patent among the Licensed Patents covers the Licensed Products in a country of the Territory, then the royalties shall be reduced to one and one-half percent (1.5%) of Net Sales of Licensed Products sold, leased, rented, licensed or otherwise distributed by Licensee in such country of the Territory.

3.2. **Milestones and Milestone Payments**. Licensee agrees to make the milestone payments to University as set forth below (the "**Milestone Payments**") within forty-five (45) days after the occurrence of each event set forth on such Schedule.

Milestone	Payment
First Phase I Clinical Trial initiated	$ 100,000
First Phase III Clinical Trial initiated	$ 350,000
First NDA Approval in the U.S	$ 500,000
First NDA Equivalent Approval outside of US	$ 500,000
Upon first $25,000,000 of commercial sales of any Licensed Products	$1,000,000

Each of the foregoing payments shall be made only once. Thereafter, no additional Milestone Payments shall be due or payable by Licensee for License Products.

3.3. **Calculations and Payment of Royalties.**

(a) Royalties shall be paid in quarterly increments (the "Royalty Period"). Royalties shall be calculated for each Royalty Period as of the last day of each such Royalty Period. Payment of Royalties with respect to each Royalty Period shall be due within sixty (60) days after the end of Royalty Period, beginning with the earlier of (i) the Royalty Period in which the first sale of a Licensed Product occurs, or (ii) the Royalty Period for which Annual Minimum Royalties are due.

(b) Within sixty (60) days of the end of each Royalty Period (whether or not Royalties are due), Licensee shall deliver to University a true and complete accounting of sales or distributions of any Licensed Product and revenues from those sales by Licensee and its Sublicensees for each country of sales origin during such Royalty Period and deductions taken, with a separate accounting for each Licensed Product of sales and receipts by country, and a detailed calculation of the Royalty payment due University for such Royalty Period, in each case in form and substance as set forth on Exhibit A attached to this Agreement. If no sales of Licensed Products were made or other payments due in such Royalty Period, then Licensee's statement shall so state.

(c) Each Annual Minimum Royalty payment shall be accompanied by a calculation of the Annual Minimum Royalty such that University can verify the amount of the payment.

3.4. **Royalty stacking and combination products**: The royalty rate will not diminish for combination products or stacking royalties.

3.5. **Annual Minimum Payments**. Beginning one year after the Licensee or any Sublicensee receives NDA approval on its first Licensed Product, it the total payments actually paid to University payments (including any payments

Company Valuation

- Most recent 10Q to get number of shares outstanding
- Share prices:
  - www.nasdaq.com/

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2019.

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____.

Commission file number 001-33528

OPKO Health, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**75-2402409**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

4400 Biscayne Blvd.
Miami, FL 33137
(Address of Principal Executive Offices) (Zip Code)

(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ YES ☐ NO

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ YES ☐ NO

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company"
(in Rule 12b-2 of the Exchange Act) (Check one):

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐
		Emerging growth company	☐

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If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): ☐ YES ☒ NO

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock	OPK	NASDAQ Global Select Market

As of April 24, 2019, the registrant had 615,601,045 shares of Common Stock outstanding.

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Opko

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- Ownership Summary

ADDITIONAL STOCK RESEARCH

View Security List	Download Security List
NASDAQ	NASDAQ (406KB)
Amex	Amex (51KB)
NYSE	NYSE (412KB)

U.S. Symbol Changes

OPKO Health, Inc. Common Stock (OPK) Quote & Summary Data

OPK $2.37* **0.04 ↓ 1.66%**

*Delayed - data as of Jul. 3, 2019 - Find a broker to begin trading OPK now

Exchange:NASDAQ
Industry: Health Care
Community Rating: Bullish

Edit Symbol List
Symbol Lookup

OPK | SGMO | CLLS | S | CRSP | EDIT | NTLA | NDAQ

Save Stocks | Refresh

SYMBOL LIST VIEWS
FlashQuotes
InfoQuotes
STOCK DETAILS
Summary Quote
Real-Time Quote
After Hours Quote
Pre-market Quote
Historical Quote
Option Chain
CHARTS
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Interactive Chart
COMPANY NEWS
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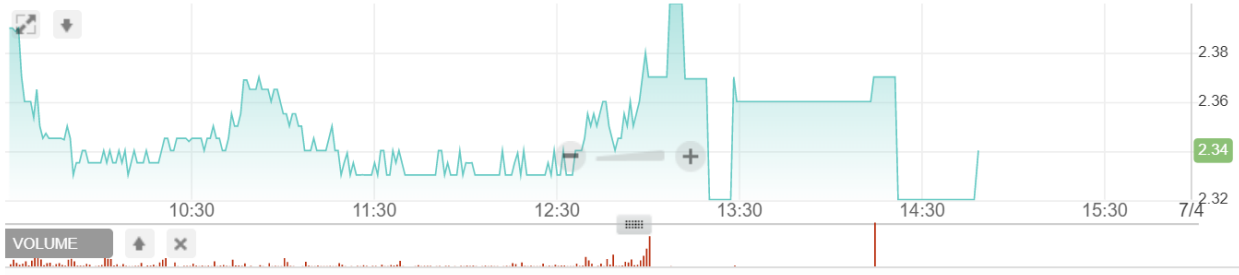
Market Stream
STOCK ANALYSIS
Analyst Research
Guru Analysis
Stock Report

Key Stock Data

Best Bid / Ask	N/A / N/A	P/E Ratio	NE
1 Year Target	4.5	Forward P/E (1y)	NE
Today's High / Low	$ 2.41 / $ 2.33	Earnings Per Share (EPS)	$ -0.33
Share Volume	2,370,522	Annualized Dividend	N/A
50 Day Avg. Daily Volume	4,944,550	Ex Dividend Date	N/A
Previous Close	$ 2.41	Dividend Payment Date	N/A
52 Week High / Low	$ 6.40 / $ 1.73	Current Yield	0 %
Market Cap	1,458,974,477	Beta	2.52

Intraday Chart



1D | 5D | 1m | 3m | 6m | 1y

More OPK Charting >

Upcoming Earnin

Company	Expect
FGP	Jun 10,
THO	Jun 10,
HDS	Jun 11,
HRB	Jun 11,
CHS	Jun 11,
AVGO	Jun 13,
TUFN	Jun 13,
CPST	Jun 11,

See Also

1 | Best Stocks To
2 | IPO Investment
3 | #1 Penny Stock
4 | Ipo Stocks To W

CONSENSUS RE

OPK $2.37* 0.04 ↓ 1.66%

*Delayed - data as of Jul. 3, 2019 - Find a broker to begin trading OPK now

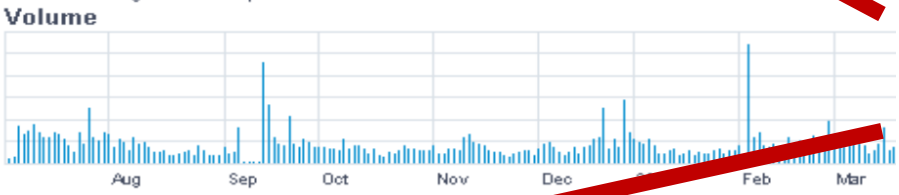
Community Rating: Bullish

Edit Symbol List
Symbol Lookup

OPK | SGMO | CLLS | S | CRSP | EDIT | NTLA | NDAQ

Save Stocks

SYMBOL LIST VIEWS
FlashQuotes
InfoQuotes
STOCK DETAILS
Summary Quote
Real-Time Quote
After Hours Quote
Pre-market Quote
Historical Quote
Option Chain
CHARTS
Basic Chart
Interactive Chart
COMPANY NEWS
Company Headlines
Press Releases
Market Stream
STOCK ANALYSIS
Analyst Research
Guru Analysis
Stock Report
Competitors
Stock Consultant
Stock Comparison
FUNDAMENTALS
Call Transcripts



The chart comes up showing a I year history. Pick 10 years and hit “Go”.

Time Frame: 1 Year

Chart Display:

Chart Type:
OHLC | Bar | Line | Candlestick | Mountain

Indicators:
Splits | Earnings *

Moving Average:
None | 20 Day | 50 Day | 200 Day

Lower Studies:

OPK $2.37* 0.04 ↓ 1.66%

*Delayed - data as of Jul. 3, 2019 - Find a broker to begin trading OPK now

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Edit Symbol List
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SYMBOL LIST VIEWS
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COMPANY NEWS
Company Headlines
Press Releases
Market Stream
STOCK ANALYSIS
Analyst Research
Guru Analysis
Stock Report
Competitors
Stock Consultant
Stock Comparison
FUNDAMENTALS
Call Transcripts

OPK | SGMO | CLLS | S | CRSP | EDIT | NTLA | NDAQ

Save Stocks

Time Frame: 10 Years

Chart Display:

Chart Type:
○ OHLC ○ Bar ○ Line ○ Candlestick ◉ Mountain

Indicators:
☑ Splits ☑ Earnings *

Moving Average:
◉ None ○ 20 Day ○ 50 Day ○ 200 Day

Lower Studies:

$2.37 x 615,601,045 shares = $1,458,974,476

If U. of IL still owned 3%, worth $43,769,234

A Newer Way to Use SEC Filings

- Companies seem to be making much more detailed disclosures of deal terms in their 10-K's these days
  - 10-K's are much easier to find and search than attached agreements
- Example
  - Asian university developing a cellular therapy
  - Model: CAR-T's
    - A leading U.S. company
      - Juno Therapeutics
        - Five academic stage deal terms identified

A Newer Way to Use SEC Filings

- Fred Hutchinson Cancer Center
  - Upfront payment of $250,000;
  - An annual maintenance fee of $50,000 for the first four years thereafter minimum annual royalties of $100,000 per year;
  - With respect to JCAR014 and JCAR017, milestone payments of $6.75 million per licensed product
  - Low single-digit royalties
    - i.e., 3-4%
  - A portion of the payments from sublicensees, on a tiered basis, up to a cap.

A Newer Way to Use SEC Filings

- Memorial Sloan-Kettering Cancer Center
  - Upfront payment of $6.9 million;
  - Annual minimum royalties of $100,000 commencing of the fifth anniversary of the agreement;
  - Mid-to-high single-digit royalties on annual net sales of licensed products or the performance of licensed services by us and our affiliates and sublicensees
    - i.e., 5-9%;
  - $6.75 million in clinical and regulatory milestone payments for each licensed product including JCAR015

A Newer Way to Use SEC Filings

- Seattle Children's Research Institute
  - Upfront payment of $200,000;
  - Annual license maintenance fees of $50,000 per year for the first five years and $200,000 per year thereafter;
  - Low single-digit royalties based on annual net sales of licensed products and licensed services by us and our affiliates and sublicensees
    - i.e., 2-4%
  - For ***JCAR014 and JCAR017***, milestone payments totaling up to $13.3 million and up to $3.0 million in commercial milestone payments;
  - A percentage of sublicensee payments up to an aggregate of $15.0 million
- **Additive to Fred Hutchinson**

A Newer Way to Use SEC Filings

- St. Jude's Children's Research Hospital
  - An upfront payment of $25.0 million;
  - Low single-digit royalties
    - i.e., 2-4%
  - $100,000 minimum annual royalty for the first two years of the agreement, and a $500,000 minimum royalty thereafter
  - Milestone payments of up to an aggregate of $62.5 million for ***JCAR014 and JCAR017***
  - A percentage of sublicense income and settlement payments.
- **Also additive to Fred Hutchinson**

Questions?

astevens@bu.edu

Break

Look forward –

Discounted Cash Flow/Net Present Value

Time Value of Money

- DCF and NPV is all about the time value of money
  - Getting $1,000 next year isn't worth as much as getting $1,000 tomorrow
  - Spending $1,000 tomorrow is worse than spending $1,000 next year
- It's just like interest, but going backwards
  - Interest rate ➔ Discount rate

Net Present Value Calculations

- Take into account the facts that:
  - Expenses are certain and early
  - Return is later and uncertain
    - Product may not succeed
    - Market may not be there

Risk-Free

- Inflation currently is around 3%
- Assume we're happy with a 7% return
  - 3% for inflation
  - 4% as a return on investment
  - No risk
- If we invested $1,000 today, we would expect $1,070 in a year
- What about the second year? Another $70?
- More:
  - For the second year, we have $1,070 invested, not $1,000
  - Expect a return of $1,070 x 0.07, i.e., $75 for the second year

Going the other way

- We want back $1,070 in a year if we invest $1,000 today
- So, we would be willing to invest $1,000 / $1,070 or $934.57 today to get $1,000 back in a year
  - 7% of $934.57 is $65.42
  - $934.57 + $65.42 = $999.99
- So the value today of $1,000 in a year's time is $934.57
  - i.e., $934.57 is the Net Present Value of $1,000 one year out with a 7% discount rate
  - 7% is the interest rate going forward, or the discount rate going backwards

Discount Rate Formula

So, the Future Value (FV) 2 years in the future is:

$$\underline{\$1{,}000} + \underline{\$1{,}000 \times 0.07} + \underline{(\$1{,}000 + \$1{,}000 \times 0.07) \times 0.07}$$

Pres. Value | Interest year 1 | Interest year 2

$$FV = PV + PV * k + (PV + PV \times k) \times k$$

or $FV = PV * (1 + k)^{2}$

So the Net Present Value (PV) of an amount FV two years in the future is

$PV = FV / (1 + k)^{2}$

We would pay today $873.44 to get back $1,000 in two years

$873.44 is the Net Present Value of $1,000 in two years with a 7% discount rate

Turns out the formula generalizes to $PV=FV / (1 + k)^{n}$

where n is the number of years in the future

Multiple Payments

- If we wanted to get back $1,000 in each of the next two years, we would be willing to pay

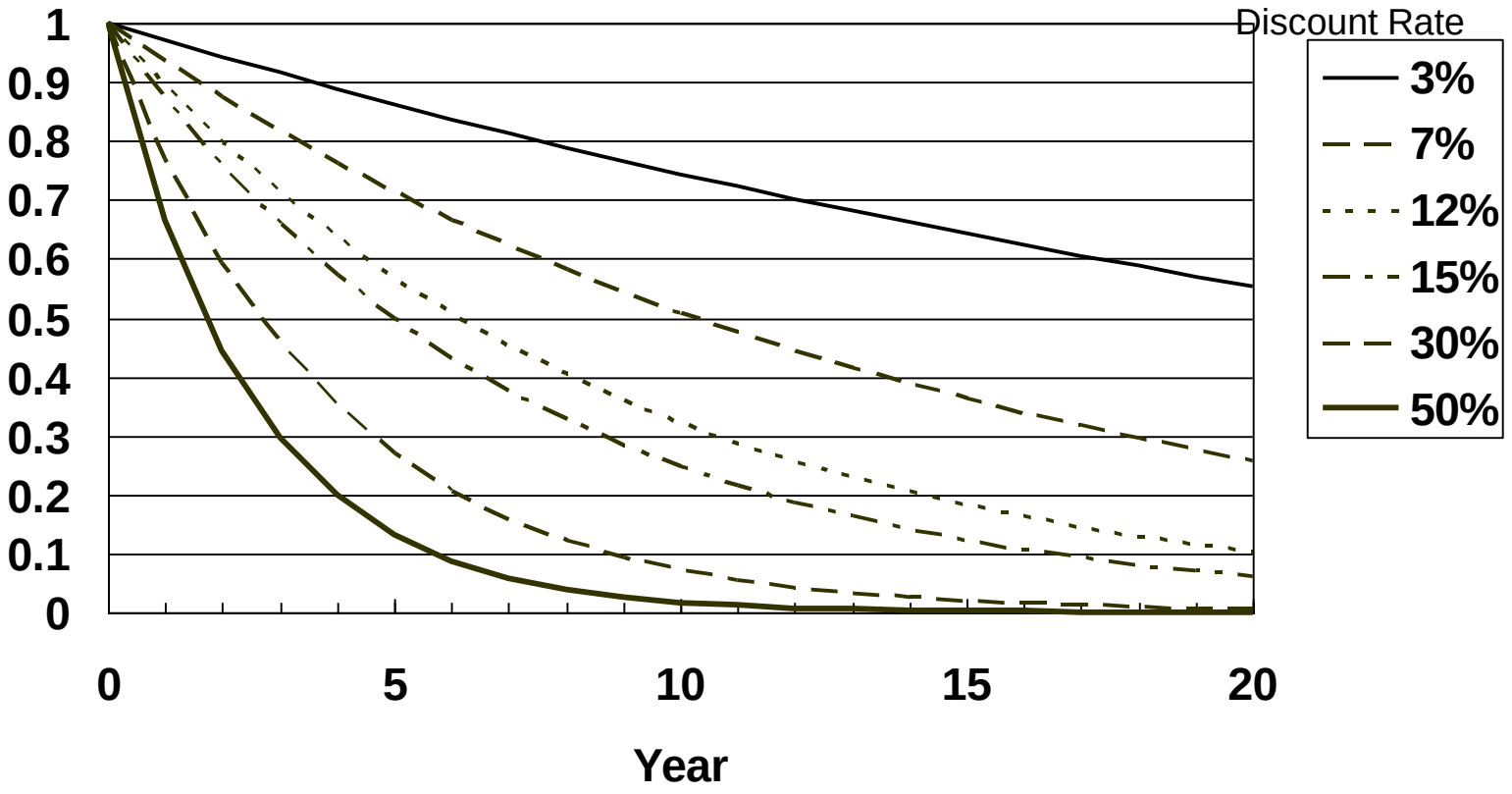
$$\$934.57 + \$873.44 = \$1,808.01$$

  - i.e., $1,808.01 is the Net Present Value of two $1,000 payments one and two years out with a 7% discount rate

Discount Rates

Inflation Rate	3%
Long Term T Bill Rate	7%
Corporate Bond Rate	12% (Blue Chip) - 18% (Junk)
Average Corporate Cost of Capital	15%
Corporate Investment Hurdle Rate	30%
VC Investment Hurdle Rate	50%

Effect of Discount Rate Over Long Periods



Net Present Value of $1,000 in Five Years

Formula is $\$1,000/(1+k)^5$

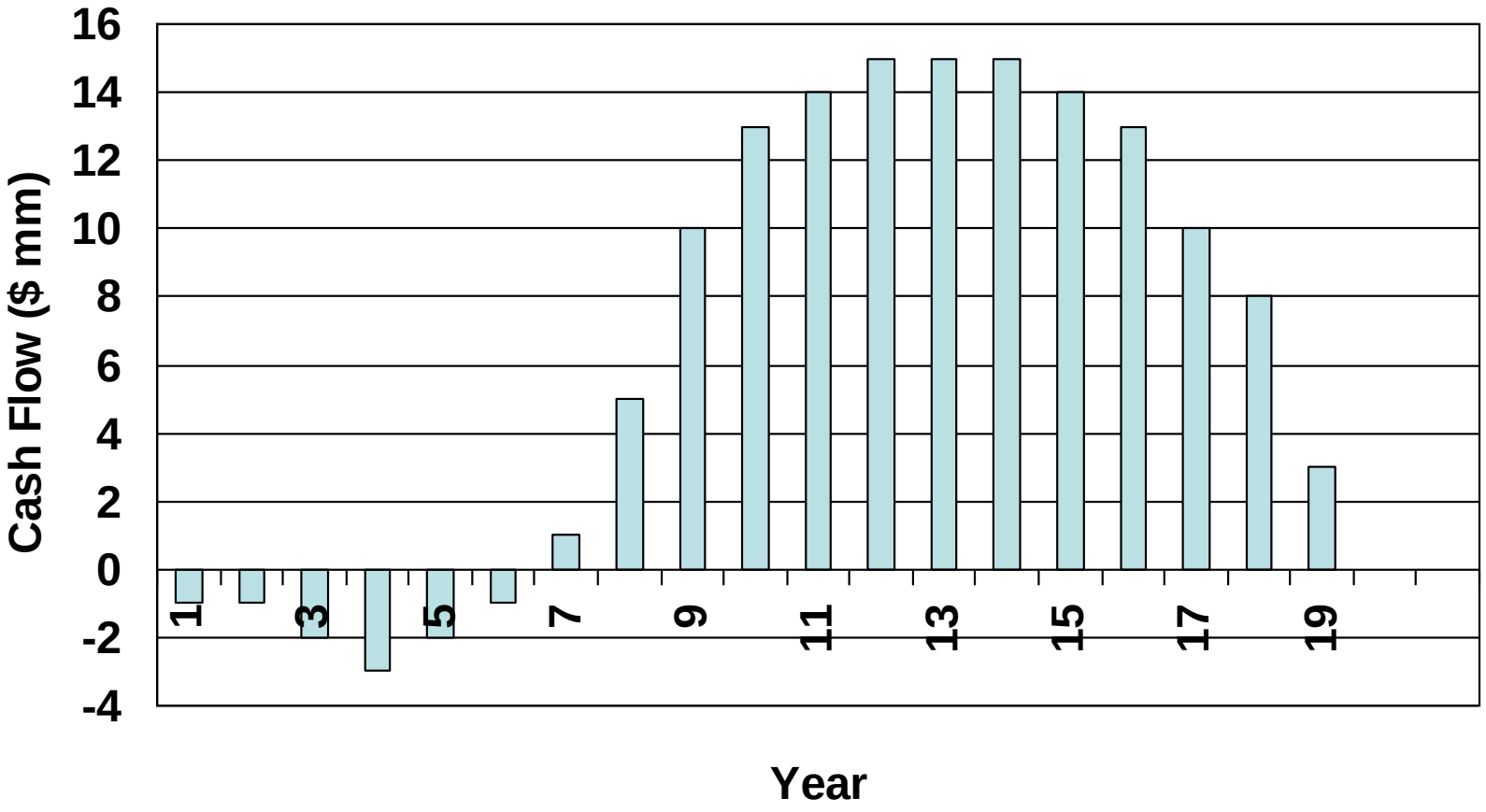
k	Value	Payback
3%	$862.61	1.15x
7%	$712.99	1.40x
12%	$567.43	1.76x
15%	$497.18	2.01x
30%	$269.33	3.71x
50%	$131.69	7.59x

A Hypothetical R&D Project

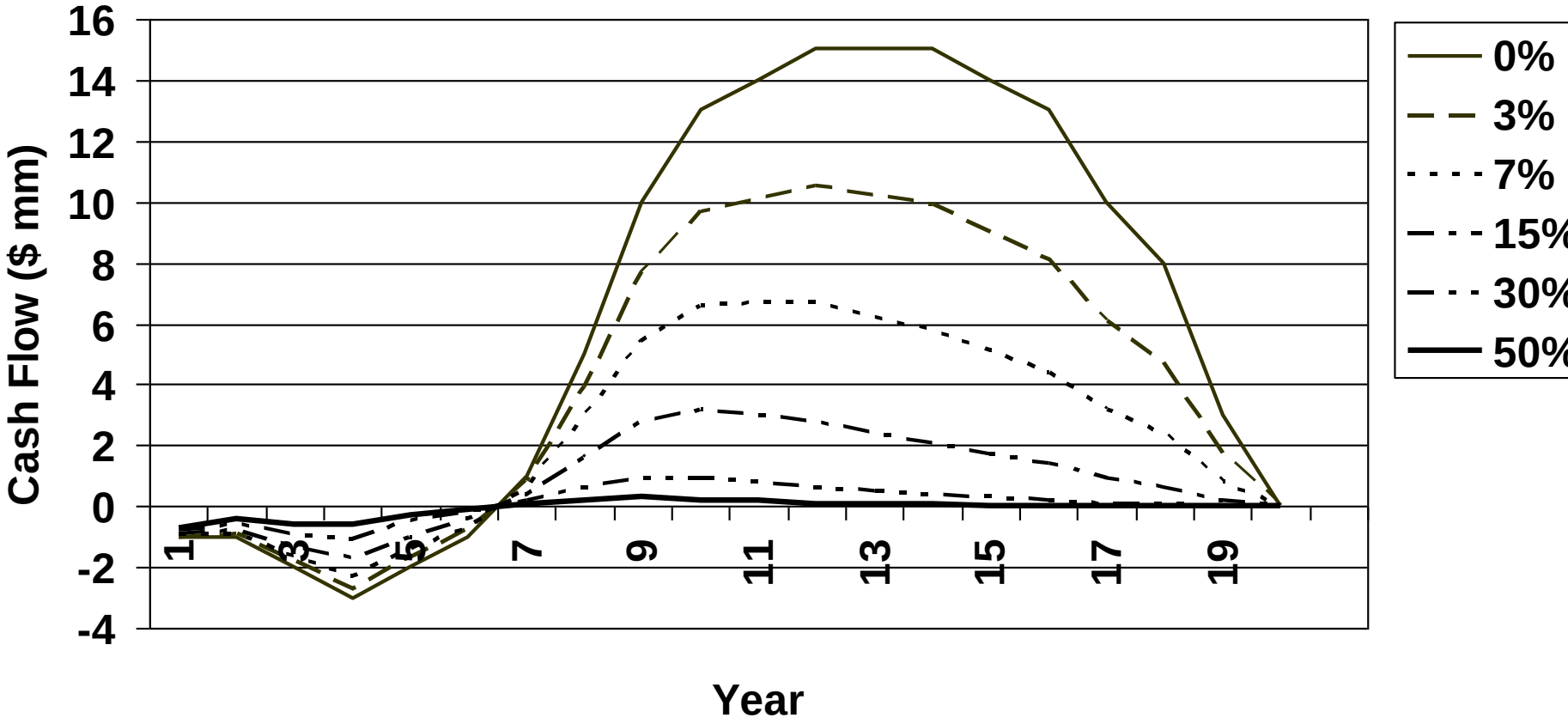
- $10 mm invested over 6 years
- Sales start in year 7
- Peak profits of $15 mm in years 12-14
- Over by year 19
- Total Net Income of $136 mm
- Net Profits exceed expenses by $126 mm

Looks like a great deal!

A Typical R&D Project



How It Looks At Different Discount Rates



So Is It Still A Good Deal?

- The answer depends on the discount rate

k	NPV	Payback
0%	$126.0 mm	12.6x
3%	$83.4mm	8.3x
7%	$49.0 mm	4.9x
15%	$17.3 mm	1.7x
30%	$1.6 mm	0.2x
50%	$(1.4 mm)	nm

Let's look at the 30% Case

- Licensee achieved their 30% return
- Project is still worth $1.6 mm today
- This amount is available to pay the licensor
- Could ask for $1.6 mm upfront -- unlikely -- puts all risk on licensee
- Some combination of upfront, milestone payments and royalty with an NPV, with a 30% discount rate, of $1.6 mm
- Assume license terms are:
- $100k upfront
- Milestone payments of $50k, $200k, $500k and $2 mm in years 3, 4, 5, 6
- Royalty rate of 5% (product has a pre-tax margin of 40%)
- NPV now ($280k)

Mechanics

- Easy to do in spreadsheets
- Excel has an NPV function
  - Handles up to 29 years
- Do your own
  - Calculate a Discount Factor for each year
  - First year is 1
  - Second year is 1/(1+k)
  - Third year is second year/(1+k)
  - Etc
  - Multiply each year's cash flow by that year's Discount Factor
  - Sum

Where Do You Get The Data?

- Ask the licensee for their projections from their business plan
- Analysts reports
- Trust, but Verify!

Risk Adjusted NPV (raNPV)

- Aka expected NPV or eNPV
- Accounting for risk through a high discount rate results in very low NPV's
- Data on drug development success rates by stage allows accounting for risk explicitly
  - Became available from Tufts Center for the Study of Drug Development in 1995
- Then use a cost of capital discount rate, frequently 10-11%
- I invented (and published!) raNPV in 1996
  - Pre State Street Bank
    - Rats!
- Big pharma's develop both NPV's and raNPV / eNPV's for projects for portfolio management purposes

FOCUS IP GROUP, LLC

Combining the 25 Percent Rule and NPV Analyses

- The Twenty Five Percent rule allocates Net Profits between licensor and licensee
  - Reflects past and future financial risk
- NPV is the best measure of Net Profits
  - It's the present value of Net Profits over the life of the project
- Apply NPV analysis of licensor's and licensee's cash flows and see how they compare
  - NPV Split analysis

NPV Split Valuation

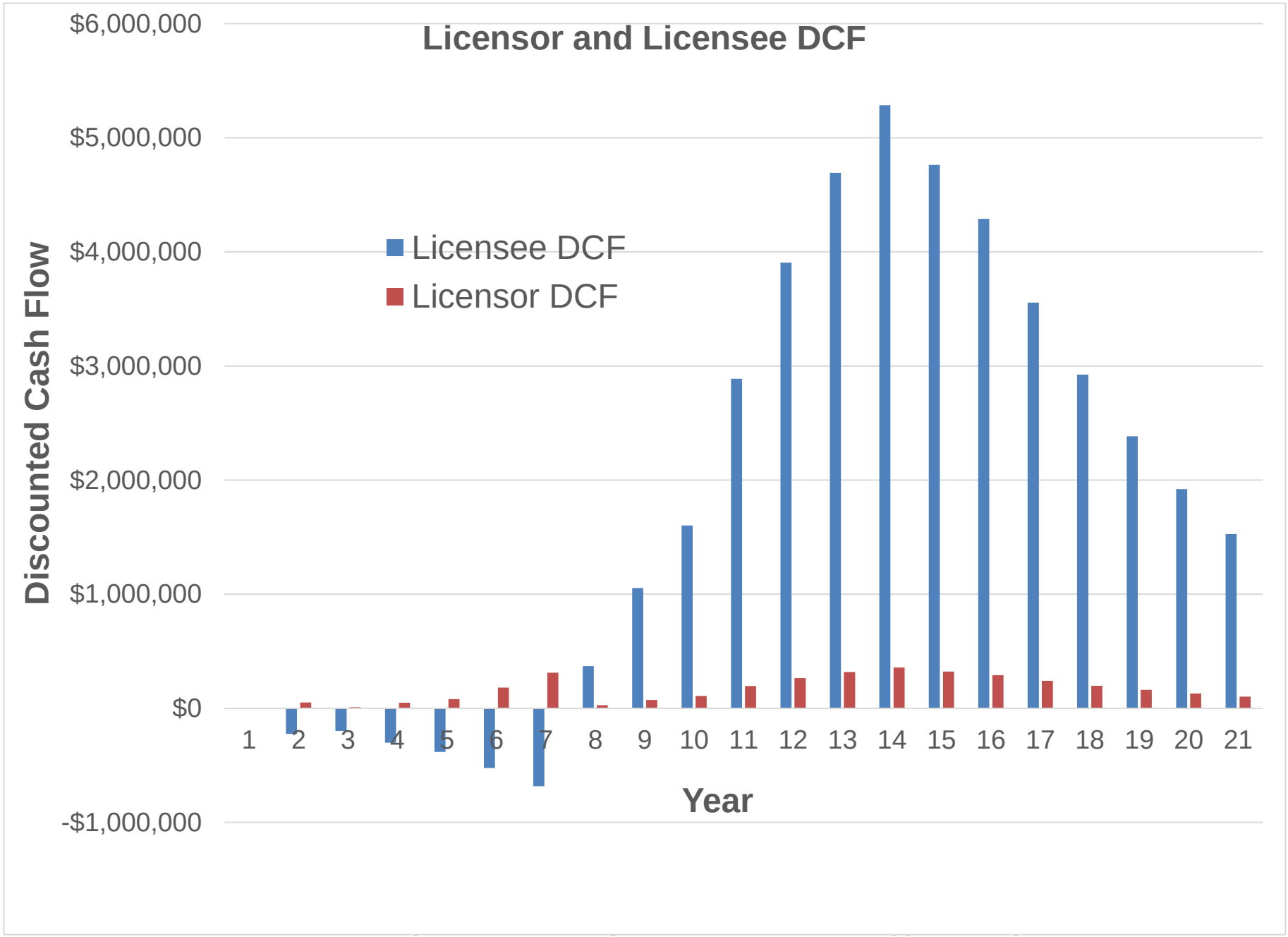
- Modelling the drug's commercialization
  - Calculate NPV
  - Create deal terms that split the NPV between licensor and licensee in percentages that depend on the stage of development of the drug
  - No "official" scale
    - Each company / B-D executive has their objectives
      - An early stage biotech entrepreneur
        - Pre-clinical 5-10%
        - Phase I 10%
        - Phase II 20%
      - A large pharma
        - Phase I 30%
        - Phase II 50%
        - Phase III 60%
        - Phase IV 70%

Example

- The Model License we looked at above
- Assume licensee's development costs are $2.1 million over years 1-6
- Assume licensee's ongoing operating costs are:
  - CoGS 5%
  - S&M 10%
  - G&A 5%
  - R&D 1%
- 11% discount rate

Product Cash Flow											
Year		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Product Sales		$ -	$ -	$ -	$ -	$ -	$ -	$ 1,000,000	$ 3,000,000	$ 5,000,000	$ 10,000,000
COGS		$ -	$ -	$ -	$ -	$ -	$ -	$ (50,000)	$ (150,000)	$ (250,000)	$ (500,000)
Patent Costs		$ (75,000)	$ (10,000)	$ (12,000)	$ (14,000)	$ (20,000)	$ (25,000)	$ (10,000)	$ (10,000)	$ (10,000)	$ (10,000)
S&M		$ -	$ -	$ -	$ -	$ -	$ -	$ (100,000)	$ (300,000)	$ (500,000)	$ (1,000,000)
G&A		$ -	$ -	$ -	$ -	$ -	$ -	$ (50,000)	$ (150,000)	$ (250,000)	$ (500,000)
R&D		$ (100,000)	$ (200,000)	$ (300,000)	$ (400,000)	$ (500,000)	$ (600,000)	$ (50,000)	$ (50,000)	$ (50,000)	$ (100,000)
Product Cash Flow		$ (175,000)	$ (210,000)	$ (312,000)	$ (414,000)	$ (520,000)	$ (625,000)	$ 740,000	$ 2,340,000	$ 3,940,000	$ 7,890,000
Discount Factors	11.0%	1.00	0.90	0.81	0.73	0.66	0.59	0.53	0.48	0.43	0.39
Product DCF		$ (175,000)	$ (189,189)	$ (253,226)	$ (302,713)	$ (342,540)	$ (370,907)	$ 395,634	$ 1,127,081	$ 1,709,670	$ 3,084,396
NPV		$42,311,251									

11	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
$ 15,000,000	$ 20,000,000	$ 25,000,000	$ 25,000,000	$ 25,000,000	$ 23,000,000	$ 21,000,000	$ 19,000,000	$ 17,000,000	$ 15,000,000
$ (750,000)	$ (1,000,000)	$ (1,250,000)	$ (1,250,000)	$ (1,250,000)	$ (1,150,000)	$ (1,050,000)	$ (950,000)	$ (850,000)	$ (750,000)
$ (10,000)	$ (10,000)	$ (10,000)	$ (10,000)	$ (10,000)	$ (10,000)	$ (10,000)	$ (10,000)	$ (10,000)	$ (10,000)
$ (1,500,000)	$ (2,000,000)	$ (2,500,000)	$ (2,500,000)	$ (2,500,000)	$ (2,300,000)	$ (2,100,000)	$ (1,900,000)	$ (1,700,000)	$ (1,500,000)
$ (750,000)	$ (1,000,000)	$ (1,250,000)	$ (1,250,000)	$ (1,250,000)	$ (1,150,000)	$ (1,050,000)	$ (950,000)	$ (850,000)	$ (750,000)
$ (150,000)	$ (200,000)	$ (250,000)	$ (250,000)	$ (250,000)	$ (230,000)	$ (210,000)	$ (190,000)	$ (170,000)	$ (150,000)
$ 11,840,000	$ 15,790,000	$ 19,740,000	$ 19,740,000	$ 19,740,000	$ 18,160,000	$ 16,580,000	$ 15,000,000	$ 13,420,000	$ 11,840,000
0.35	0.32	0.29	0.26	0.23	0.21	0.19	0.17	0.15	0.14
$ 4,169,864	$ 5,009,904	$ 5,642,498	$ 5,083,331	$ 4,579,578	$ 3,795,519	$ 3,121,885	$ 2,544,489	$ 2,050,874	$ 1,630,103


Licensor and Licensee DCF
$6,000,000
$5,000,000
$4,000,000
$3,000,000
$2,000,000
$1,000,000
$0
-$1,000,000
Discounted Cash Flow
Licensee DCF
Licensor DCF
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
Year

Example

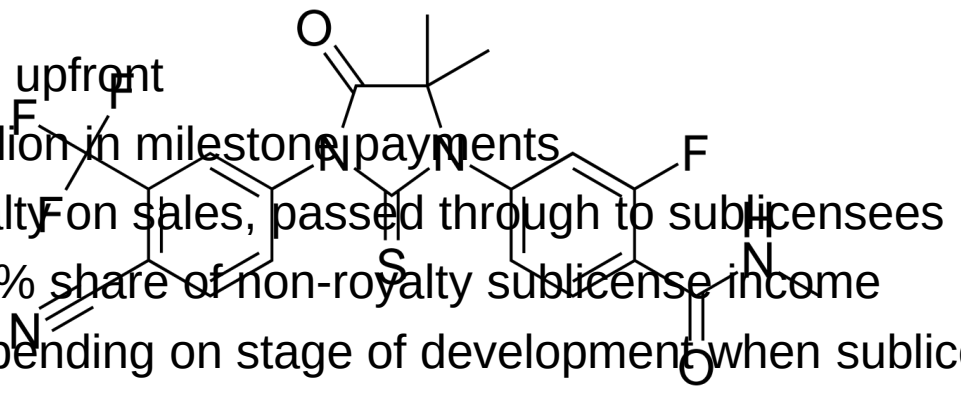
- NPV of the drug is $42.3 million
  - NPV for the licensee is $38.8 million
  - NPV for the licensor is $3.5 million
    - NPV Split is 8.2%: 91.8%
- What if licensor's VP Research insists on a 10% NPV split?
- Use Goal Seek:
  - Set Licensor NPV split = 10%
  - Vary running royalty rate
    - ➔ 6.4%

Late Stage Drug Deals

- Phase III drug deals frequently are 50:50
  - Co-development
  - Co-promotion
  - 50:50 profit split
- Example: Medivation-Astellas – Xtandi

UCLA / Medivation / Astellas / Pfizer

- Medivation licensed ~170 diarylthiohydantoin compounds from UCLA in 2005
  - The RD Series
    - Bind and inhibit the androgen receptor
  - Preclinical
    - $15,000 upfront
    - $2.8 million in milestone payments
    - 4% royalty on sales, passed through to sublicensees
    - 25%-10% share of non-royalty sublicense income
      - Depending on stage of development when sublicense done



- RD162' became Xtandi®
  - Best drug for advanced prostate cancer
  - 2019 sales ~$4 billion

UCLA / Medivation / Astellas / Pfizer

- In 2009, Medivation did a deal with Astellas
  - Drug just entering Phase 3
  - $110 million upfront
  - $335 million in development milestone payments
  - $320 million in sales milestone payments
  - 50 : 50 co-development and profit sharing in U.S.
  - Running royalties in RoW tiered low teens to low twenties;
    - Assume same as 2008 Medivation-Pfizer Alzheimer's/Parkinson's deal done in 2008:
      - 12% up to $500 million
      - 16% up to $1 billion
      - 20% up to $1.5 billion
      - 24% over $1.5 billion

Look at the Build Up in Value

- 2005 $3 million
- 2009 $775 million
- 2016 $15.4 billion

NPV Analysis

- Sales Forecast
  - Actual sales through 2016
    - Medivation's 10-K's
  - Analysts reports 2016-2021
  - Grow at 14.3% through August 2027
    - Orange Book patent expiration
  - Assume 50:50 split US:RoW after 2019
- Profitability
  - Assume US profitability of 65% continues and applies in RoW

UCLA / Medivation / Astellas / Pfizer

- NPV's 2009:
  - UCLA: $716 million 2.9%
  - Medivation: $9,899 million 40.1%
  - Astellas: $14,086 million 57.0%

- Why does Astellas get 57% when co-development / co-promotion / 50:50 profit split
  - Medivation bore all costs up to Phase III
  - Medivation only gets tiered royalties in RoW

UCLA / Medivation / Astellas / Pfizer

- In March 2016, UCLA monetized its royalty rights for $1.14 billion
  - Having already received ~$300 million in running royalties and sublicense income sharing payments
    - Model says $1.105 billion
- In August 2016, Pfizer acquired Medivation for $14 billion
    - Model says $16 billion

List Pricing

- As you get more familiar with tech transfer and do more deals, you'll have a good feel for what they're worth
  - Won't need to go through a specific valuation exercise for each one

And if all else fails……..

5%

THIS INDENTURE made this 30th day of May, A.D.

1922

BETWEEN

The Governors of the University of Toronto,

of the First Part;

-and-

The Eli Lilly Company, Incorporated under the laws of the State of Indiana, of Indianapolis, in Marion County and State of Indiana.

of the Second Part.

WHEREAS the Party of the First Part is the owner of a pancreatic extract or product for the treatment of diabetes mellitus and a process for preparing the same for which application for Letters Patent was filed in the United States Patent Office on or about the 22nd day of May, A. D. 1922 under Serial Number 562, 835.

AND WHEREAS the party of the First Part is not in a

Patent granted for the said process and product and any improvements thereto, on the same favourable terms as other firms similarly licensed by the said party of the first part and the said party of the second part in consideration of the said license shall pay to the party of the first part a royalty of 5% of the net selling prices which the said party of the second part receives for the product, during the life of such patent.

(10) In the event of the said party of the second part, during the said experimental period or subsequently during the period of the license referred to in paragraph 9, shall develop, improve, or simplify methods of producing the said pancreatic extract, full and complete information regarding such methods shall be communicated by the party of the second part to the said party of the first part for use in the preparation of the said extract.

For More Information

- Intellectual Property Valuation Manual For Academic Institutions
  - Ashley J. Stevens
    - World Intellectual Property Organization (WIPO), Geneva, Switzerland, March 2016,
    - Available at: http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=332588

Questions?

Case Study 1 – Juno vs. Kite

Juno vs Kite

- Juno and Memorial Sloan-Kettering sued Kite over Yescarta® in October 2017
  - 7,446,190
    - Expires May 2023
  - Kite bought by Gilead for $11.9 billion in August 2017
  - Juno bought by Celgene for $9 billion in January 2018
    - Celgene bought by BMS for $74 billion in January 2019
- Yescarta ® approved October 2017
  - Relapsed / refractory large B-cell lymphoma
    - 2019 sales $489 million
    - 2022 forecast $1.47 billion
  - BMS awarded $752 million in damages in December 2019

Let's Do an NPV Analysis of Yescarta

- First construct sales projections
  - Actual sales are available for 2017-2019 from Juno's SEC filings
  - Projection to 2022 available

Yescarta®

		2017	2018	2019	2020	2021	2022	2023
Sales		$20	$264	$489	$750	$1,100	$1,470	$819

Royalty Rate

- We have the MSK-Juno deal terms
  - Mid-to-high single-digit royalties
    - i.e., 5-9%
      - Use 7%

Yescarta®

		2017	2018	2019	2020	2021	2022	2023
Sales		$20	$264	$489	$750	$1,100	$1,470	$819
Royalties	7.0%	$ 1	$ 18	$34	$53	$77	$103	$57

Discount

- Inflate past royalties to mid-2019
- Discount future royalties back to mid-2019
  - 11% discount rate is standard

Yescarta®

		2017	2018	2019	2020	2021	2022	2023
Sales		$20	$264	$489	$750	$1,100	$1,470	$819
Royalties	7.0%	$ 1	$ 18	$34	$53	$77	$103	$57
Discount rate	11%	1.23	1.11	1	0.90	0.81	0.73	0.66

Yescarta®

		2017	2018	2019	2020	2021	2022	2023
Sales		$20	$264	$489	$750	$1,100	$1,470	$819
Royalties	7.0%	$ 1	$ 18	$34	$53	$77	$103	$57
Discount rate	11%	1.23	1.11	1	0.90	0.81	0.73	0.66
Discounted royalties		$1.72	$20.51	$34.23	$47.30	$62.49	$75.24	$37.74
Total								$279.24

Reconciliation

- NPV is $279.24 million
  - Award was $756 million
- Use Goal Seek function under What If Analysis in Data tab of Excel
  - Set NPV to $756 million
  - Vary Royalty Rate to get there

Yescarta®

		2017	2018	2019	2020	2021	2022	2023
Sales		$20	$264	$489	$750	$1,100	$1,470	$819
Royalties	18.9%	$4	$50	$92	$141	$207	$277	$154
Discount rate	11%	1.23	1.11	1	0.90	0.81	0.73	0.66
Discounted royalties		$4.65	$55.24	$92.18	$27.37	$168.30	$202.62	$101.64
Total								$752.00

Reconciliation

- Juno-MSK License 7%
- Litigation 18.9%

- Reasons:
  1. In litigation, patent is presumed valid and infringed
     - In licensing, uncertainty as to validity
  2. In litigation, royalty is determined on the eve of infringement
     - Later of patent issuance and product launch
       - License is done at much earlier stage
       - Royalty rates for marketed products much higher than for preclinical / Phase 1 products

Questions?

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