

Session 10 : Understanding the activities of a TTO

Valuation

Ashley Stevens

Who's Speaking



Ashley Stevens

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Dr. Stevens is a biotech entrepreneur and technology commercialization expert. He co-founded Genmap, Inc. and Kytogenics, Inc., bringing academic innovations to market. He later led technology transfer at Dana-Farber Cancer Center and Boston University, where he helped launch 55 startups.

Affiliation

- Past President Association of University Technology Managers, USA (AUTM)
- Head of Tech Transfer for Boston University
- President Focus IP Group, LLC

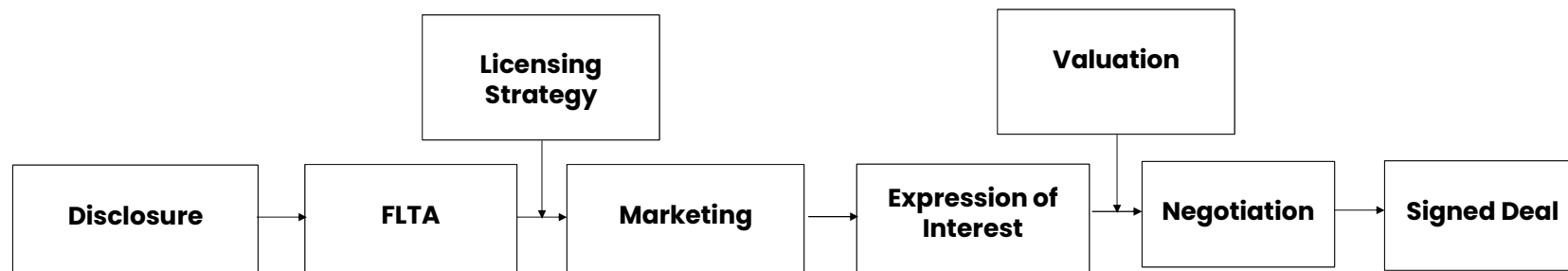


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The Technology Transfer Process



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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

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

Valuation



Pricing

- With a valuation basis
- Without a valuation basis

- You negotiate the bases
- You negotiate from emotions

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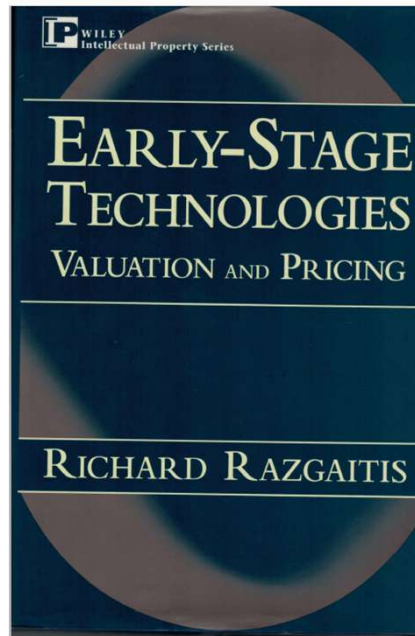
When Is Technology Valued?

› 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

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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**

What do we Mean by the “Value” of a Deal?



ABOUT SCIENCE PRODUCTS RESPONSIBILITY STORIES

Newsroom Partners Investors  Careers 



Amgen and Generate Biomedicines Announce Multi-Target, Multi-Modality Research Collaboration Agreement

Companies Partner to Leverage Generate’s Machine Learning-Enabled Technology Platform to Discover and Create Protein Therapeutics for Patients

THOUSAND OAKS, Calif. & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 6, 2022-- Amgen (NASDAQ: AMGN) and Generate Biomedicines today announced a research collaboration agreement to discover and create protein therapeutics for five clinical targets across several therapeutic areas and multiple modalities. As part of the research collaboration, Amgen will pay \$50 million in upfront funding for the initial five programs with a potential transaction value of \$1.9 billion plus future royalties, and will have the option to nominate up to five additional programs, at additional cost. For each program, Amgen will pay up to \$370 million in future milestones and royalties up to low double digits. Amgen will also participate in a future financing round for Generate. Additional terms were not disclosed.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20220106005262/en/>

“We are now at a scientific hinge point, where computational approaches can advance our knowledge of biology and further drive our ability to design the right molecule for some of the most challenging targets,” said David M. Reese, M.D., executive vice president of Research and Development at Amgen. “We believe Generate Biomedicine’s integrated in silico design and wet lab capabilities combined with Amgen’s strength in protein engineering can accelerate our drug discovery efforts, generating novel protein sequences with optimal therapeutic properties.”

Recognizing the unique discovery challenges in multispecific drug discovery, Amgen has invested over the last decade in the marriage of wet lab high throughput automation and dry lab computational biology. Amgen’s generative biology strategy has led to the building of a Digital Biologics Discovery group, to harness the Company’s pioneering strength in biology, automation, and protein engineering. The goal of generative biology at Amgen is to take this experience and expertise in biologics combined with emerging sequence-based drug design technologies to deliver complex multispecific medicines against a variety of difficult-to-treat diseases. Combining Amgen’s biologics drug discovery expertise with the power of Generate Biomedicines Artificial Intelligence (AI) platform provides the opportunity to further facilitate multispecific drug design by shaving time off discovery timelines and generating potential lead molecules that have predictable manufacturability and clinical behavior.

Generate Biomedicines is pioneering the field of generative biology – a revolutionary approach to drug discovery and development that leverages machine learning and AI to program novel protein therapeutics. The company’s machine learning algorithms analyze hundreds of millions of known proteins, looking for statistical patterns linking amino acid sequence, structure and function, and its technology platform has been enhanced by closed-loop learning on tens of thousands of computationally generated and broadly experimental characterized

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Risk

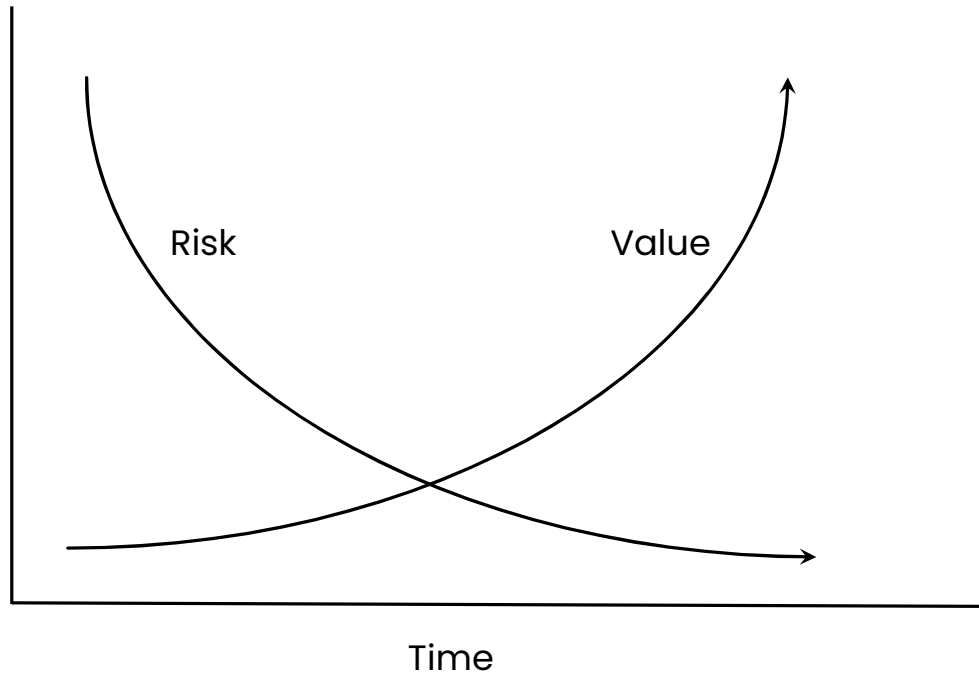
Types of Risk

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

Overall

- › 1 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



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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 ~\$2 billion in royalties
 - UFL gets 20%
 - Cade Trust gets 80%

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

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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

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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)

An Example – mRNA Vaccines

- Aka Moderna and Pfizer / BioNTech
- Key enabling technology is the 2005 Weissman / Karikó
 - uridine → pseudouridine
 - cytidine → 5-methylcytidineone
 - substitution technology
 - Penn filed patents in 2006
- Founded RNARx in 2007
 - Got \$97,396 SBIR
 - Got further \$900,000 SBIR
 - Ceased operations in 2013
 - Didn't license the Penn patents
 - Penn licensed Cellscript / mRNA Ribotherapeutics in Wisconsin
 - \$300,000 upfront
 - mRNA Ribotherapeutics sublicensed Moderna and BioNTech

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An Example – mRNA Vaccines

› License terms

	<u>Moderna</u>	<u>BioNTech</u>
Upfront	\$75 million	
Milestones	\$26 million	\$26 million
Running royalty rate	3.5%	Low-to-mid single digits

› Moderna paid \$641 million in 2021

- Pfizer's sales were ~2x Moderna's
- Total royalties ~\$2 billion

› Penn's royalty income:

- 2020 \$30.6
- 2021 \$310.2
- 2022 \$1,258.6

› But could it have been \$2 billion?

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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:
$$\text{Royalty payments} = \text{Royalty base} * \text{Royalty rate}$$
 - 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

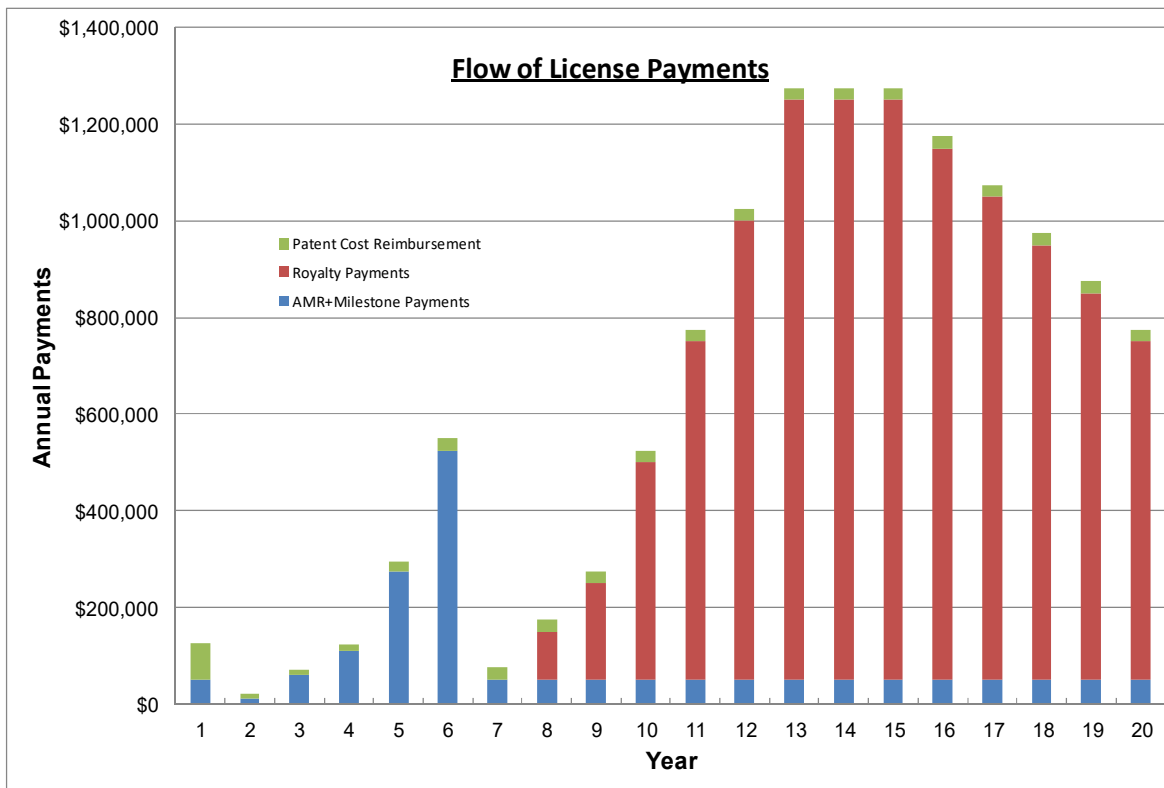
Example

- › 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

<u>Year</u>	<u>Product Sales</u>
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

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How to Allocate Value to Inventors and Patents

- Allocating value to inventors:
 - Default position – Equal shares
 - Unless all sign an agreement to unequal shares
 - Can include non-inventors
 - If all agree
- Allocating value to patents
 - May require some judgement
 - E.g.: A drug
 - Composition of value patent most valuable
 - Method of treating, formulation, manufacturing less valuable

How to Allocate Value to Institutions

- › Can be very tricky
- › Do it per patent in the technology bundle
 - Quantitative approaches:
 - Research expenditures at each institution
 - Number of inventors
 - Remember: Always have a defensible basis for your proposals

Example

» Drug

- Composition of matter 100% Institution 1
- Method of treating 50 : 50
- Formulation 100% Institution 2

» Allocate weights

- Composition of matter 3
- Method of treating 1
- Formulation 0.5

» Weighted contribution Institution 1 Institution 2

• Composition of matter	300	
• Method of treating	50	50
• <u>Formulation</u>	--	<u>50</u>
Total	350	100
	78%	22%

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

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Today

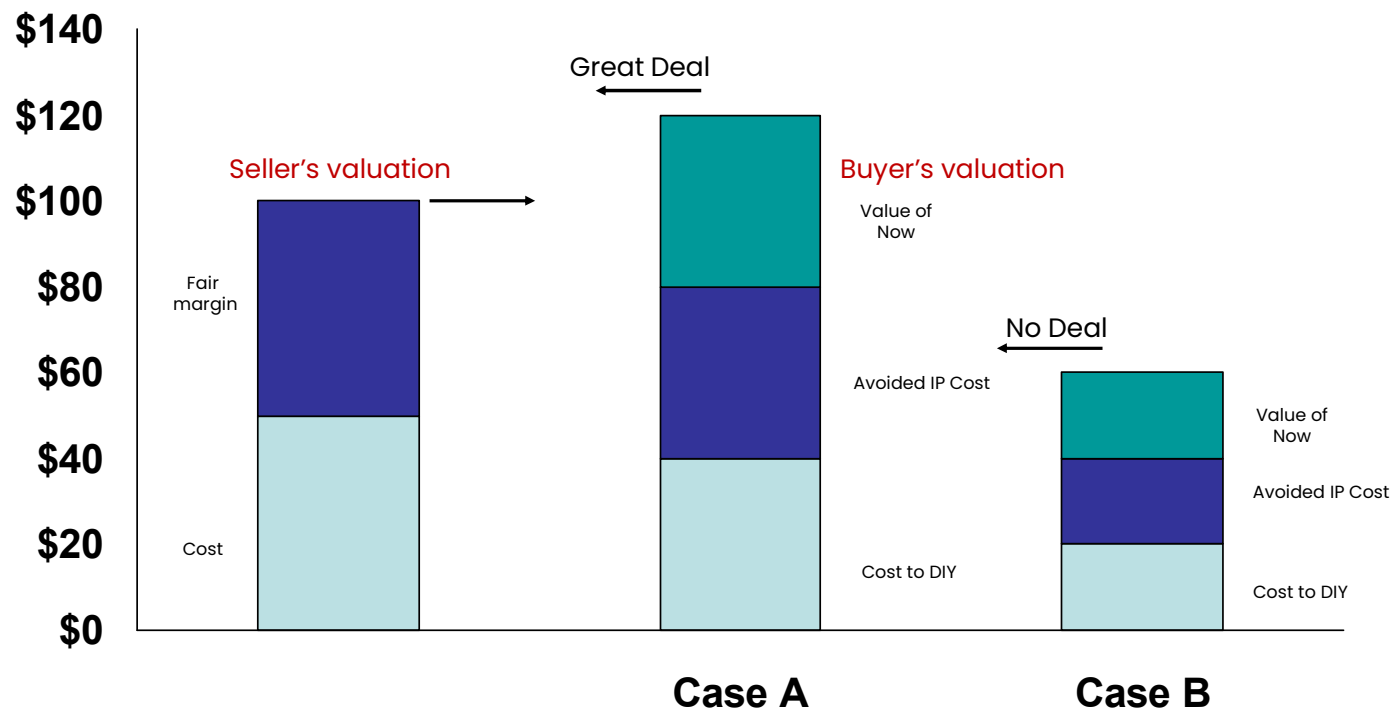
- › Cost
- › Rules of Thumb
- › Industry Standards – Comparables
- › Discounted Cash Flow

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



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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

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A Fundamental Principle of Technology Valuation

The Goldscheider Principle (aka the 25% Rule)

“The Licensors should receive 25% and the Licensee should receive 75% of the pre-tax profits from a licensed product”

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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
- › Applicable to fully enabling technology
 - Need to prorate if other IP also needed
- › Applied to fully-loaded pre-tax profits, not gross margin

Application

- › Expressed as a % of net sales in license
 - Royalty rate = 25% x expected pre-tax profit margin
- › Example for a patent that fully enables the product:
 - \$200 sale price
 - \$100 Cost of Goods Sold (COGS)
 - \$50 SR&A
 - = \$50 Pre-tax Profit
 - Patent owner share: $0.25 \times \$50 = \12.5
 - Royalty = $\$12.5 / \$200 = 6.25\%$
 - Patent 75% enables product: Royalty = 4.69%
 - Patent 50% enables product: Royalty = 3.13%
 - Patent 10% enables product: Royalty = 0.63%

Application

- › Good starting point for negotiation
 - But almost never the final rate agreed to
- › Adjusted according to “enabling value” (%)
 - Typically after analysis of:
 - Manufacturing cost,
 - Market pricing dynamics
 - Value-add by licensee....
- › Round off the numbers
 - 4.5% not 4.69%
 - 3.0% not 3.13%
 - 0.5% not 0.63%
- › Limited value in academic licensing negotiations because of early stage
 - Incomplete cost data available
 - Very helpful when you’re licensing to a new industry

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The 25% Rule and the Supreme Court

- » In 2011 *Uniloc vs Microsoft* decision, Supreme Court determined that the 25% Rule was too imprecise an instrument to compute damages in infringement cases;
 - Goldscheider wrote a passionate defense in *les Nouvelles*
 - To no avail
 - Died July 2012
- » Still a valid and important methodology in licensing

Other Examples of Risk Transfer Revenue Sharing

- ▶ The 25 Percent Rule type of split shows up in different sectors
 - Seems to be frequently perceived as “fair” when the future risk is transferred from one party to another
 - Our own royalty sharing policies
 - The inventor has largely completed their part
 - The Institution is taking on the financial risk of patenting and marketing
 - Common income sharing arrangements:
 - 1/3rd / 1/3rd / 1/3rd
 - 25% / 25% / 25% / 25%

Other Examples of Risk Transfer Revenue Sharing

- ▶ Sublicense Income Sharing
 - Licensors' investment is complete
 - Licensee is taking the technology forward
 - 25% is a good starting point for negotiating sublicense income sharing

Other Examples of Risk Transfer Revenue Sharing

▶ Oil and gas royalties

- The landowner has made its investment in buying the land
 - Will make no contribution to extracting the resources
 - Oil / gas company takes on the financial risk of drilling
- Royalty rates:¹
 - Federal land 12.5%
 - First Biden auction 18.75%
 - Federal waters 12.5-18.75%
 - State land 16.67-20%
 - Private land 12.5-25%

¹ <https://www.doi.gov/sites/doi.gov/files/report-on-the-federal-oil-and-gas-leasing-program-doi-eo-14008.pdf>

Other Examples of Risk Transfer Revenue Sharing

Table 1: Technology Fee for Biotech Planting Seed in Argentina

Year	Price of Biotech Seed US\$/Ha		
	Bollgard	Roundup Ready	Bollgard + Roundup Ready
1998/99	76.0	Not approved	-
1999/00	70.0	Approved	-
2000/01	60.0		-
2001/02	60.0	30.0	-
2002/03	60.0	30.0	-
2003/04	40.0	30.0	-
2004/05	40.0	30.0	-
2005/06	40.0	30.0	-
2006/07	40.0	20.0	-
2007/08	40.0	20.0	-
2008/09	40.0	20.0	-
2009/10	Stopped	120.0	Approved
2010/11	-	120.0	160.0
2011/12	-	120.0	155.0
2012/13	-	120.0	150.0
2013/14	-	80.0	150.0
2014/15	-	80.0	150.0

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We'll return to this later in NPV split analyses

Look Around – Industry Standards/Comparables

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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 & Deal Terms Survey – 2021

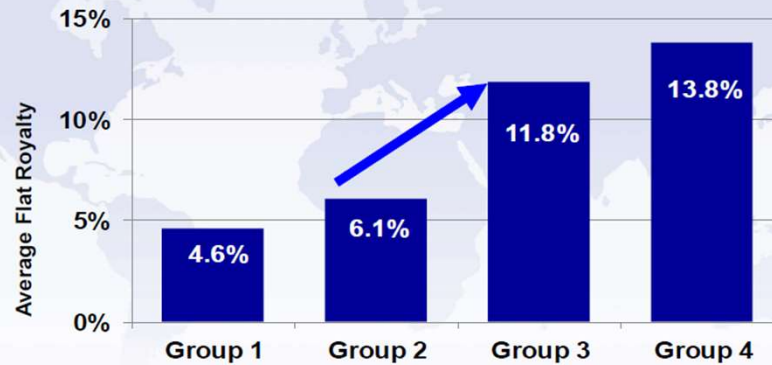
- › 116 complete and used
- › Oncology, CNS, Respiratory, Immunological, Blood & Clotting, and Infectious Disease were the most prevalent
- › 84% were exclusive
- › 59% included U.S. and 54% were global
- › 61% pre-IND
 - Very useful for universities
- › 50% had expected peak sales >\$500 million
- › Royalty structure
 - 53 fixed royalties
 - 54 tiered royalties
 - 9 no royalty
 - 2% profit share

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Flat Royalties - Combined Surveys

Average Royalty by Stage of Development

Drawing information from across the six most recent surveys reveals a substantial increase in royalty rate for assets that have achieved proof of concept.



No. of Deals	104	20	20	26
Min	1%	1%	1%	1%
Median	4%	4%	11%	9%
Max	35%	20%	35%	50%



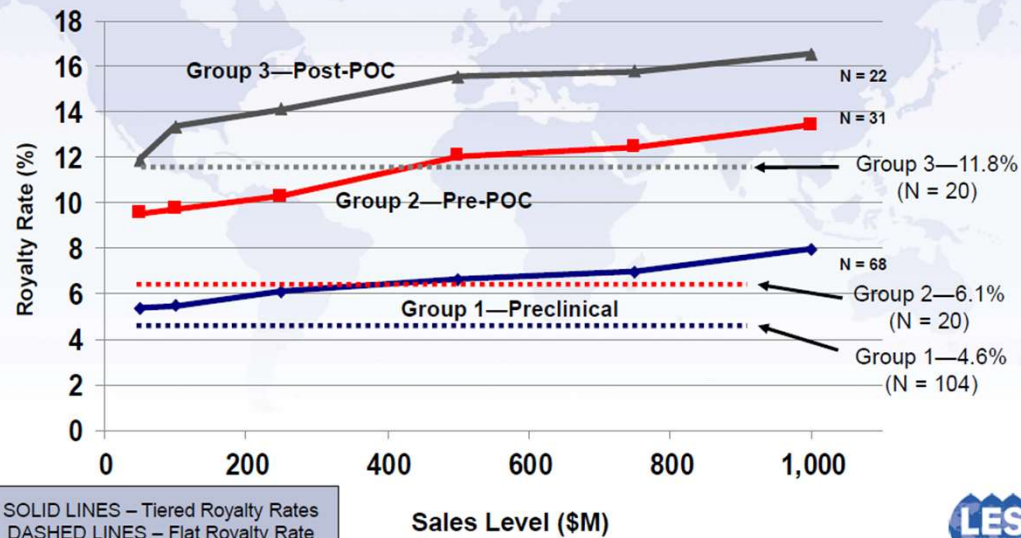
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58

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Comparison of Flat and Tiered Royalties Combined Surveys

The robust data set built from the five surveys supports expectations for increasing royalties as a product matures through development.



85

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- › 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

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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
- Much more user friendly now
- 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

RoyaltyStat

Business Valuation Resources

royaltysource.com/
www.royaltystat.com/
www.bvresources.com/

Life Sciences

Clarivate (former ReCap)

BioScience Advisors

IQVIA (former PharmaDeals)

www.cortellis.com/intelligence
www.biosciadvisors.com
www.pharmadeals.net/

- › 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

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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

Waiting for www.cortellis.com...

The screenshot displays the Cortellis website interface within a web browser. The browser's address bar shows the URL <https://www.cortellis.com/intelligence/home.do>. The Cortellis logo is prominently displayed on the left. To the right, there are links for 'Explore', 'en', 'Help', and 'Stevens Ashley', along with the 'Clarivate Analytics' logo. A search bar is located in the center, containing the text 'siRNA', which is circled in red. Below the search bar are buttons for 'Index' and 'Full Text'. Underneath the search bar, there are links for 'Advanced search' and 'Structure search'. The main content area features three sections: 'Competitive Intelligence', 'Deals Intelligence', and 'News', each with a dropdown arrow and a plus sign. A 'Live chat' button is visible in the bottom right corner of the main content area. The Windows taskbar at the bottom shows the search bar with the text 'Type here to search' and various application icons. The system clock indicates the time is 2:25 AM on 7/3/2019.

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Cortellis

siRNA

Index

Full Text

Explore

en | Help
Stevens Ashley

Clarivate
Analytics

Advanced search | Structure search

< Back | Forward > Search Results

Save and Alert

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548 results found for index Search for the search term 'siRNA'

First Previous 1 2 3 4 5 6 7 8 9 10 Next Last

Report Type	Deal Title	Principal Company	Partner Company	Deal Asset Type	Deal Transaction Type	Deal Status
Show selected only				Filters: [0]	Filters: [0]	Filters: [0]
Companies (2)						
Deals (548)	Arcturus and Ultragenyx to discover and develop mRNA therapeutics using UNA Oligomer chemistry and LUNAR nanoparticle delivery platform	Arcturus Therapeutics Inc (Pharma)	Ultragenyx Pharmaceutical Inc (Biotech)	Drug Discovery Technology	Collaboration (Shared responsibilities); License Option (Option to take a license)	Active
Press Releases (2028)						
Venture Funding (6)						
Refine Search						
Search within Results	NCI to award PDX Pharmaceuticals funding for development of PDX-001 against breast cancer	PDX Pharmaceuticals (Biotech)	National Cancer Institute (Government agency)	Capital(Grants/Loans/Equity Inv./ Royalty buyouts); Drug	Grant	Active
▼ Drug Development Status						
▼ Drug Highest Status (Deal Start)	Regeneron and Alnylam to discover, develop and commercialize RNAi therapeutics for ocular and CNS diseases worldwide	Alnylam Pharmaceuticals Inc (Pharma)	Regeneron Pharmaceuticals Inc (Biotech)	Drug Discovery Technology; Drug	Equity/Equity Option (Licensee invests in Licensor company); Collaboration (Shared responsibilities); License Option (Option to take a license)	Active
Discovery (178)						
Preclinical (164)						

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A Deal Title	B Principal Company	C Principal Company Type	D Partner Company	E Partner Company Type
1 Arcturus and Ultragenyx to discover and develop mRNA therapeutics using UNA	Arcturus Therapeutics Inc	Pharma	Ultragenyx Pharmaceutical Inc	Biotech
2 NCI to award PDX Pharmaceuticals funding for development of PDX-001 against breast	PDX Pharmaceuticals	Biotech	National Cancer Institute	Government agency
3 Regeneron and Alnylam to discover, develop and commercialize RNAi therapeutics for	Alnylam Pharmaceuticals Inc	Pharma	Regeneron Pharmaceuticals Inc	Biotech
4 Janssen to develop and commercialize Arrowhead's ARO-HBV, with an option to	Arrowhead Pharmaceuticals Inc	Pharma	Janssen Pharmaceuticals Inc	Pharma
5 Nitto Denko and Osaka International Cancer Institute to develop new nucleic acid	Nitto Denko Corp	Other (non industrial)	Osaka International Cancer Institute	Other (non industrial)
6 Genzyme to develop Alnylam's RNAi therapeutics worldwide, excluding North	Alnylam Pharmaceuticals Inc	Pharma	Sanofi Genzyme	Biotech
7 Thea to develop and commercialize OliX's OLX-301A against age-related macular	OliX Pharmaceuticals Inc	Pharma	Laboratoires Thea	Biotech
8 Karolinska Institute to conduct clinical trial for Alnylam Pharmaceuticals' givosiran for acute	Karolinska Institute	Academic	Alnylam Pharmaceuticals Inc	Pharma
9 Medison Pharma to commercialize Alnylam's RNAi therapeutics for rare diseases in Israel	Alnylam Pharmaceuticals Inc	Pharma	Medison Pharma Ltd	Biotech
10 Covance to provide OliX with GLP toxicology study services for OLX-10020 against GA	Covance Inc	Biotech	OliX Pharmaceuticals Inc	Pharma
11 OliX Pharmaceuticals and University of Virginia School of Medicine to conduct	University of Virginia School of Medicine	Academic	OliX Pharmaceuticals Inc	Pharma
12 Dicerna and Boehringer to discover and develop GalXC RNAi therapeutics for NASH	Dicerna Pharmaceuticals Inc	Pharma	Boehringer Ingelheim International GmbH	Pharma
13 Aro Biotherapeutics to develop and commercialize Janssen's Centvrin protein	Janssen Pharmaceuticals Inc	Pharma	Aro Biotherapeutics Co	Pharma

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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

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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

RECAP IQ by Deloitte Ashley Stevens My Projects My Account Help Recap.com

DEAL builder VALUATION analyzer DEVELOPMENT optimizer

Home > Deal Home Page > Alliance Search Builder > Alliance Summary

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-β expression silencing by siRNA for ophthalmic diseases

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

SNAPSHOT:

Trends in Discovery Deal Terms: siRNA Technology for Gene Silencing

University of Illinois → **Acuity**

Acuity → **Opko Health, Inc.** (through a reverse merger with eRegenics, Inc. in 3/07)


Acuity shall manufacture

Recombinant Capital www.recap.com

LICENSE

Exclusivity:	Exclusive	Licensed Territory:	Worldwide
Licensed Use:	Diseases	Licensed Country:	
Notes:	Field of Use shall mean the inhibition and treatment of ophthalmic disease.		

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Search

Index

Help

[Home](#) > [Deal Home Page](#) > [Alliance Search Builder](#) > [Alliance Summary](#) > [Contract Analysis](#)

Contract Analysis

R&D Company: University of Illinois
Client Company: Acuity Pharmaceuticals
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		

R&D Parent:
Client Parent: Opko Health

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 Proptix Corporation ("Proptix"), both privately owned, became Opko Health, Inc. ("Opko") through a reverse merger with publicly-traded eXegenics, Inc. (see Separate Deal Background -- Opko / Acuity, Proptix 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 counterparts: (List CON) "Technical Information" shall mean the nonpatented technical information and know-how belonging to the University that is

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Site Search

Search
Index
Help

Home > Deal Home Page > Alliance Search Builder > Alliance Summary > Contract

Contract

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

Alliance Type:	License	Date:	08/2006
Contract Type:	License	Revision:	
		Filing Date:	08/2006

CONTENT: EX-10.8 8 g06337env10w8.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 ACUTY 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 β 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 I 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.

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obligation to provide Licensee or any Sublicensee with any updates or of 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:

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

4

- 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.
- 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.
- 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.


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Home > Deal Home Page > Alliance Search Builder

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, Froptx / Opko Health	03/2007	Acq, Mrg					Reverse merger with eXogenics to form Opko Health
2		University of Illinois / Acuity Pharmaceuticals	08/2006	L	\$2.5	\$0.0	\$1.5	3.0%	TGF-β expression silencing by siRNA for ophthalmic diseases
3		ZaBeCor / Acuity Pharmaceuticals	04/2006	L, O					Excellair anti-inflammatory siRNA for Ophthalmic 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/Tolentino)

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Opko Health, Inc. CIK#: 0000944809 (see all company filings)

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)
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MIAMI FL 33137
305-575-4138

Mailing Address
4400 BISCAYNE BLVD.
MIAMI FL 33137

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Items 1 - 40 [RSS Feed](#)

Next 40

Filings	Format	Description	Filing Date	File/Film Number
8-K	Documents	Current report, item 5.02 Acc-no: 0000944809-19-000043 (34 Act) Size: 37 KB	2019-07-03	001-33528 19940837
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	2019-06-21	001-33528 19911939
SC 13D	Documents	General statement of acquisition of beneficial ownership Acc-no: 0001193125-19-171306 Size: 124 KB	2019-06-12	
SC 13D	Documents	General statement of acquisition of beneficial ownership Acc-no: 0001193125-19-171303 Size: 117 KB	2019-06-12	
SC 13D	Documents	General statement of acquisition of beneficial ownership Acc-no: 0001193125-19-171298 Size: 113 KB	2019-06-12	
SC 13D	Documents	General statement of acquisition of beneficial ownership Acc-no: 0001193125-19-171297 Size: 116 KB	2019-06-12	
8-K	Documents	Current report, item 7.01 Acc-no: 0000944809-19-000039 (34 Act) Size: 30 KB	2019-06-06	001-33528 19881561
8-K	Documents	Current report, item 8.01 Acc-no: 0000944809-19-000036 (34 Act) Size: 28 KB	2019-05-17	001-33528 19835621
SC 13D	Documents	General statement of acquisition of beneficial ownership	2019-05-09	



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formerly: eXegenics Inc (filings through 2007-06-13)
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Next 40

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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	001-33528 071285385
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	001-33528 071275314
8-K	Documents	Current report, items 5.02 and 8.01 Acc-no: 0000950144-07-008821 (34 Act) Size: 12 KB	2007-09-25	001-33528 071134508
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	000-26648 07843418
8-K	Documents	Current report, item 1.01 Acc-no: 0000950144-07-003524 (34 Act) Size: 11 KB	2007-04-18	000-26648 07773324
8-K	Documents	Current report, items 4.01, 5.02, and 9.01 Acc-no: 0000950144-07-003401 (34 Act) Size: 47 KB	2007-04-18	000-26648 07765640
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	000-26648 07735592
8-K	Documents	Current report, items 3.03 and 9.01 Acc-no: 0001144204-07-014826 (34 Act) Size: 44 KB	2007-03-21	000-26648 07722221
8-K	Documents	Current report, items 3.02, 5.01, 5.02, 8.01, and 9.01	2007-02-09	000-26648

Form 8-K - Current report: SEC Accession No. 0000950144-07-002945

Filing Date 2007-04-02 Accepted 2007-04-02 07:13:22 Documents 22	Period of Report 2007-03-27	Items Item 1.01: Entry into a Material Definitive Agreement 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
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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		2166581

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.: 000-26548 | Film No.: 07735592

Business Address
1250 PITTSFORD-VICTOR ROAD
BUILDING 200, SUITE 280
PITTSFORD, NY 14850

Mailing Address
1250 PITTSFORD-VICTOR ROAD
BUILDING 200, SUITE 280
PITTSFORD, NY 14850

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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 β 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

- 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;

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.**

4

- (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
(State or Other Jurisdiction of
Incorporation or Organization)

75-2402409
(I.R.S. Employer
Identification No.)

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

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X
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Tags
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(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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

[Table of Contents](#)

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	TRK	NASDAQ Global Select Market
As of April 24, 2019, the registrant had 615,601,045 shares of Common Stock outstanding.		

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Enter symbol, name or keyword

Comfort Inn* Concord
Concord, NH

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Stock Analysis	Fundamentals	Holdings/Ownership
<ul style="list-style-type: none"> Analyst Research Stock Reports 	<ul style="list-style-type: none"> Financials Revenue/EPS SEC Filings Short Interest Dividend History 	<ul style="list-style-type: none"> Ownership Summary

ADDITIONAL STOCK RESEARCH

View Security List	Download Security List
<ul style="list-style-type: none"> NASDAQ Amex NYSE 	<ul style="list-style-type: none"> NASDAQ (406KB) Amex (51KB) NYSE (412KB)

U.S. Symbol Changes

Comfort Inn* Concord
Concord, NH

QANTAS
Two holidays. One simple fare.

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Home > Quotes > **OPK**

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

OPK SGMO CLLS S CRSP EDIT NTLA NDAQ

☐ Save Stocks Refresh

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

More OPK Charting >

Upcoming Earnings

Company	Expected Report Date
FGP	Jun 10, 2019
THO	Jun 10, 2019
HDS	Jun 11, 2019
HRB	Jun 11, 2019
CHS	Jun 11, 2019
AVGO	Jun 13, 2019
TUFN	Jun 13, 2019
CPST	Jun 11, 2019

[Earnings Calendar >](#)

See Also

- 1 | Best Stocks To Invest In
- 2 | IPO Investment Strategy
- 3 | #1 Penny Stock to Hold
- 4 | Ipo Stocks To Watch

CONSENSUS RECOMMENDATION

Buy

News for OPK

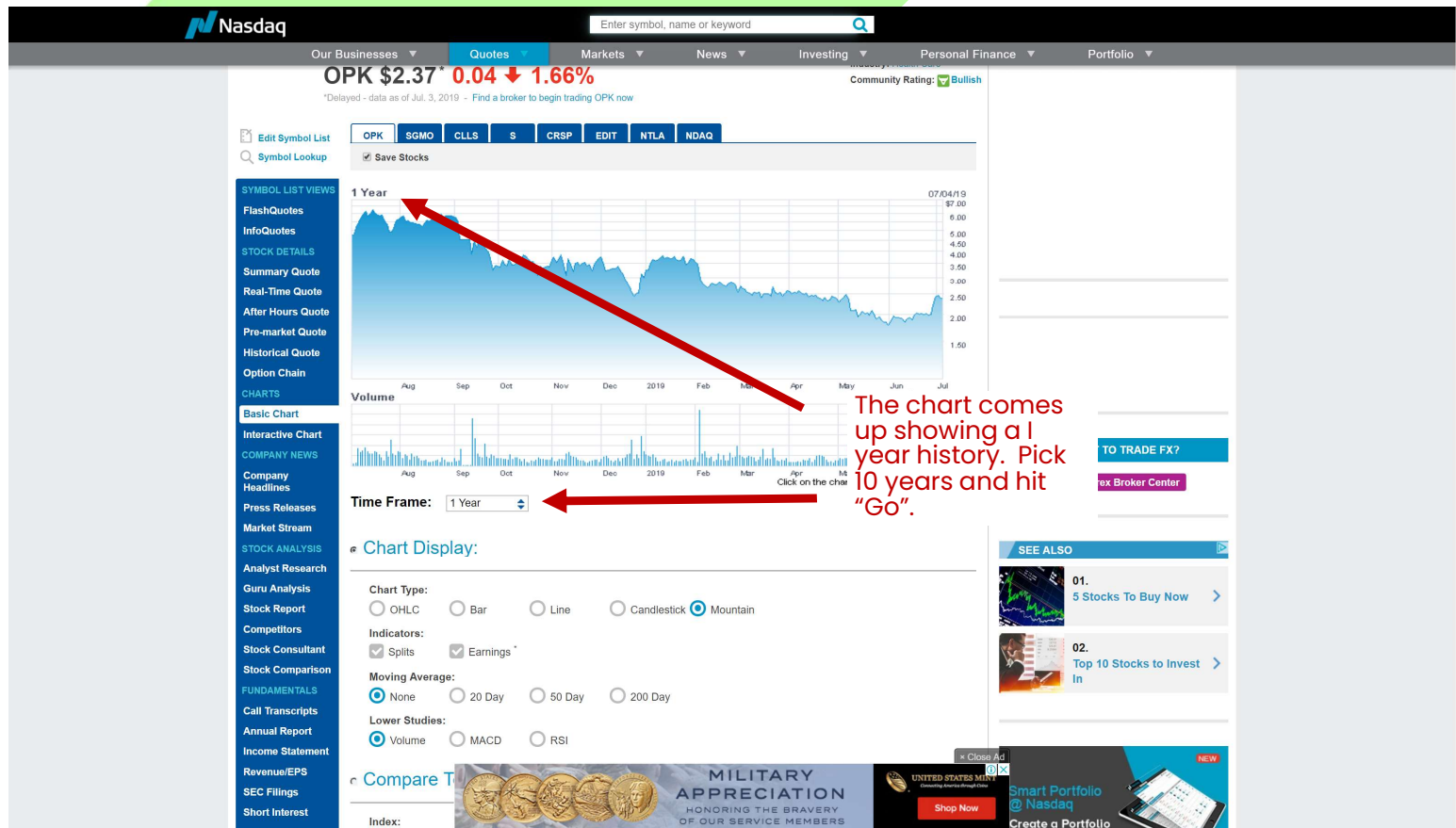
Why OPKO Health Stock Jumped Today

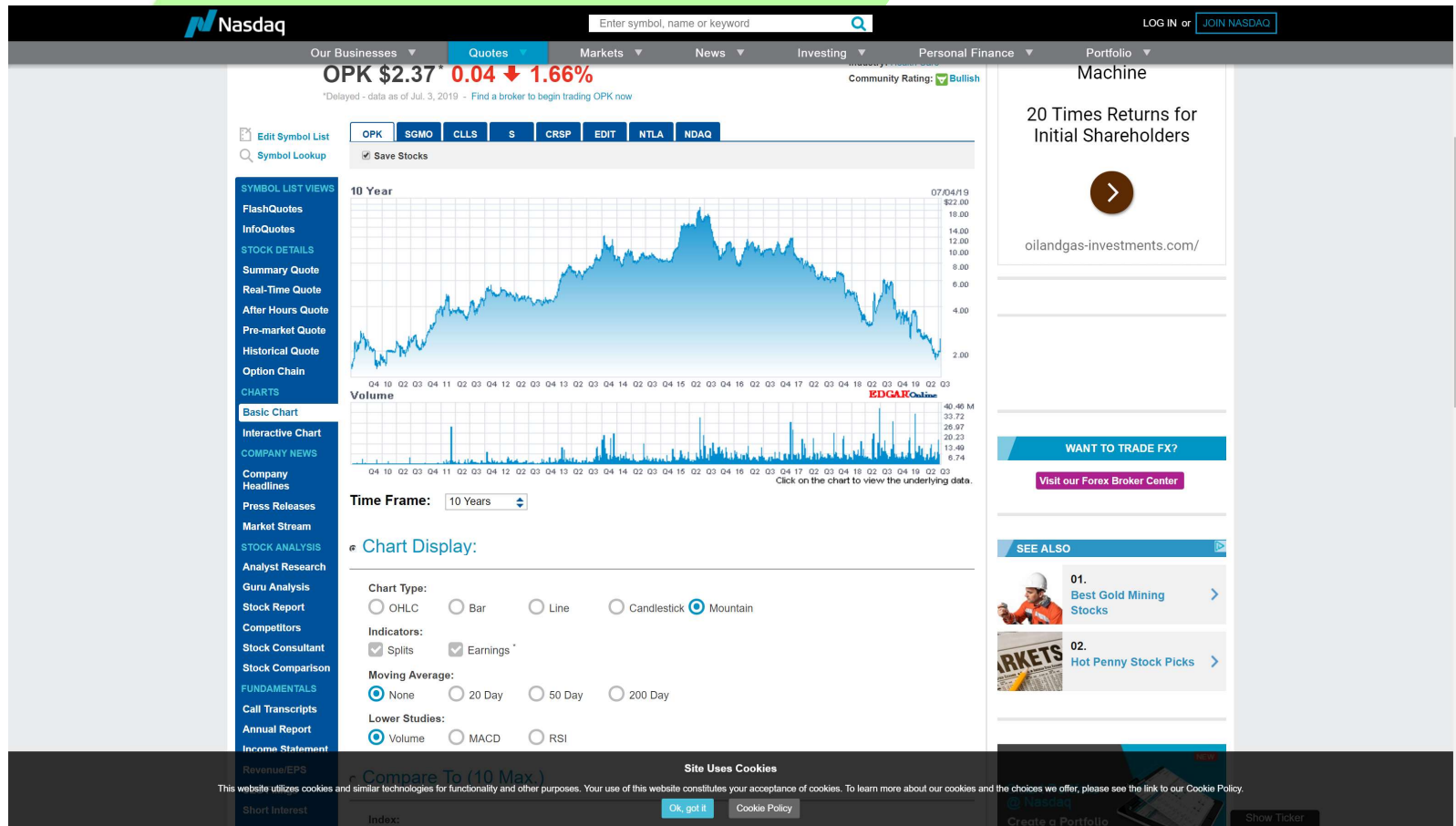
Jul 3, 2019 5:00:00 PM - Market Watch

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$\$2.37 \times 615,601,045 \text{ shares} = \$1,458,974,476$

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

Lunch Break

Session 11:

Understanding the activities of a TTO

Valuation (continued)
Exercise 3 : Valuation

Ashley Stevens, Neha Jacob, Premnath V

Who's Speaking



Ashley Stevens

PhD, CLP, RTTP

Dr. Stevens is a biotech entrepreneur and technology commercialization expert. He co-founded Genmap, Inc. and Kytogenics, Inc., bringing academic innovations to market. He later led technology transfer at Dana-Farber Cancer Center and Boston University, where he helped launch 55 startups.

Affiliation

- Past President Association of University Technology Managers, USA (AUTM)
- Head of Tech Transfer for Boston University
- President Focus IP Group, LLC



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Who's Speaking



Neha Jacob
CA, CS

Neha is responsible for general management and strategic initiatives at Venture Center. Her role involves developing, building and managing infra, resources & processes, and setting up platforms to support scale up of activities at Venture Center, thereby giving momentum to the startup ecosystem. At Venture Center, she has contributed to the production of the [AIM-PRIME playbook](#), meant as a practical guide for deep tech entrepreneurs – available on Amazon, globally. She has worked on technology and company valuation exercises. She is also involved in the fundraising efforts and developing partnerships and collaborations for the organisation.

Affiliation

- Head-Operations, Venture Center



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Who's Speaking



Premnath Venugopalan PhD, RTTP, FSTEM

Dr. Premnath, Director of Venture Center and Head of NCL Innovations, is a leader in technology transfer, IP commercialization, and venture creation. He has shaped national policies and established award-winning innovation management initiatives, fostering technology commercialization, startups, and deep-tech incubation across India through CSIR-NCL and Venture Center.

Affiliation

- Director, Venture Center, Pune



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Valuation (continued)

Ashley Stevens

Look forward –
Discounted Cash Flow/Net Present Value

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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 $\$1,070 \times 0.07$, 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:

$$\begin{array}{ccccccc} \$1,000 & + & \$1,000 \times 0.07 & + & (\$1,000 + \$1,000 \times 0.07) \times 0.07 \\ \uparrow & & \uparrow & & \uparrow \\ \text{Pres. Value} & & \text{Interest year 1} & & \text{Interest year 2} \end{array}$$

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

$$\text{or } FV = PV \times (1 + k)^2$$

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%

Net Present Value of \$1,000 in Five Years

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

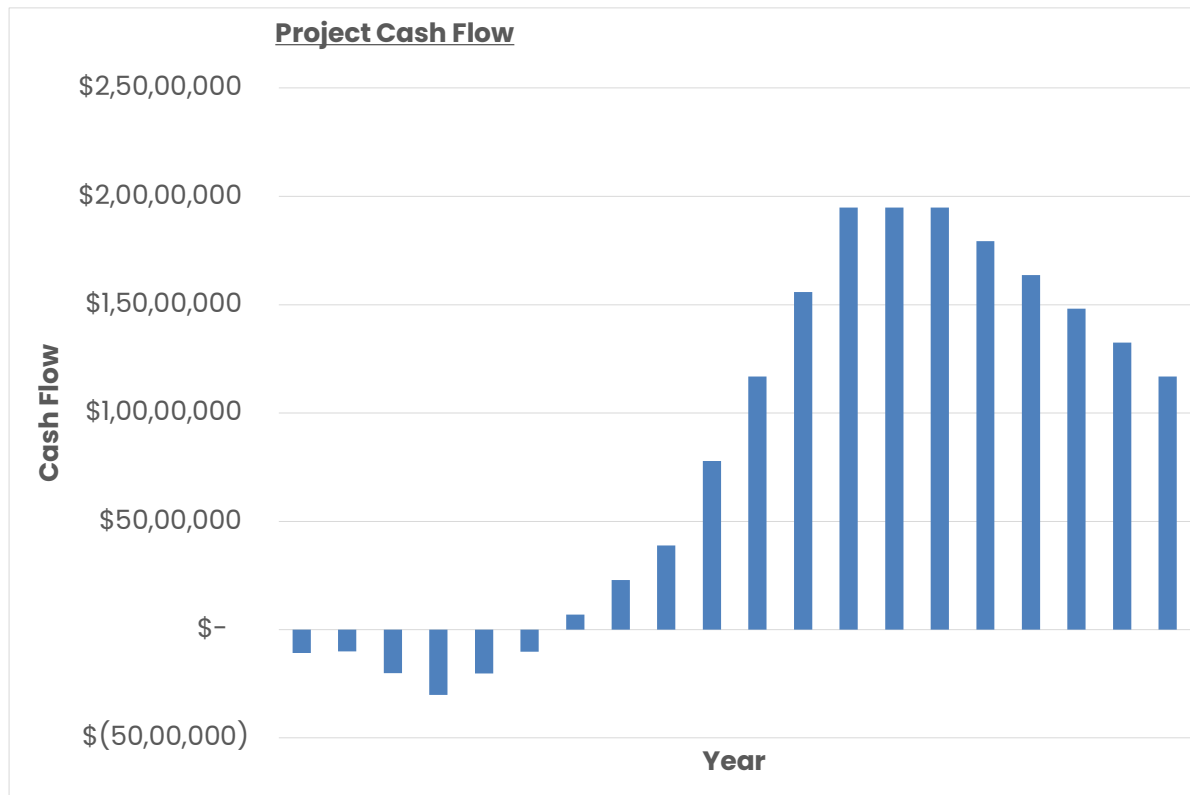
k	Value	Payback
3%	\$862.61	1.15x
7%	\$712.99	1.40x
12%	\$567.43	1.76x
15%	\$497.18	2.01x
30%	\$269.33	3.71x
50%	\$131.69	7.59x

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Let's Look at the Licensed Project we Looked at Earlier

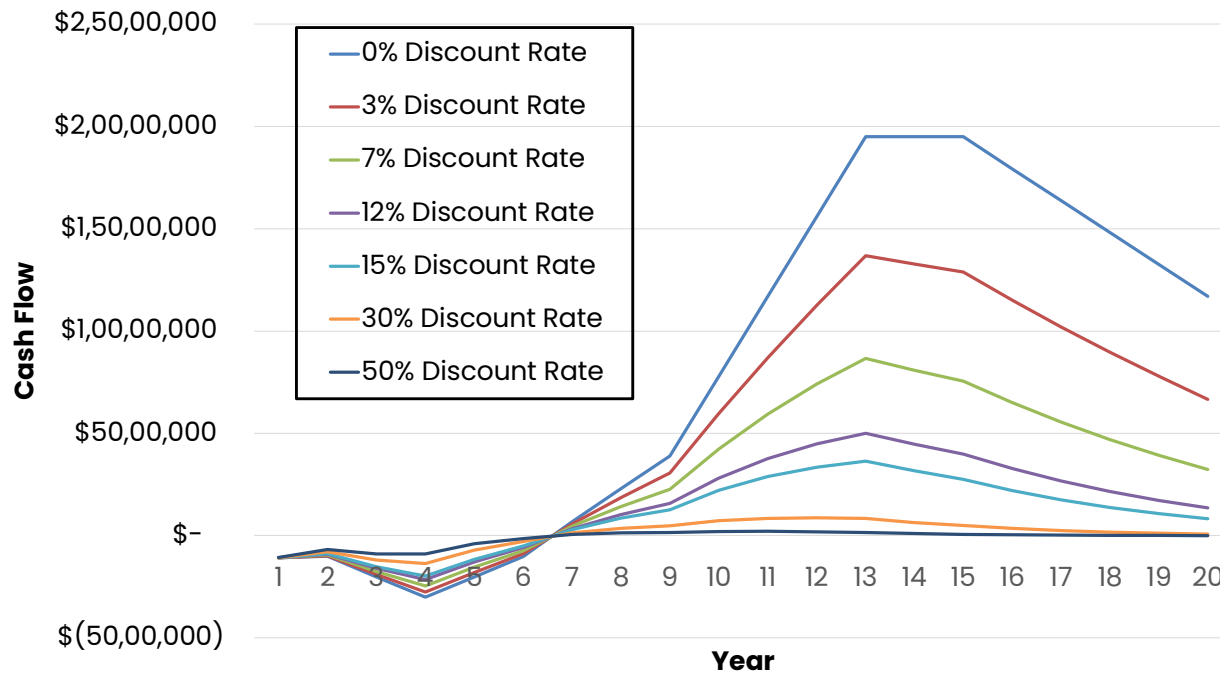
- › \$10 million invested over 6 years
- › Sales start in year 7
- › Operating costs
 - CoGS 5%
 - S&M 10%
 - G&A 5%
 - Ongoing R&D 2%
- › Peak profits of \$18 million in years 12-14
 - Declining to \$11 million in year 20
- › Total Net Income of \$174 million
 - Net Profits exceed investment by \$164 million

Looks like a great deal!



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Project Cash Flow at Different Discount Rates



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So Is It Still A Good Deal?

- › The answer depends on the discount rate

<u>K</u>	<u>NPV</u>	<u>Payback</u>
0%	\$164.3	16.4x
3%	\$107.0	10.7x
7%	\$61.4	6.1x
12%	\$31.1	3.1x
15%	\$20.6	2.1x
30%	\$1.0	0.1x
50%	\$(2.7)	NM

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Let's look at the 30% Case

- › Licensee achieved their 30% return
- › Project is still worth \$979,937 today
- › This amount is available to pay the licensor
- › Could ask for \$979,937 upfront
 - Unlikely -- puts all risk on licensee
- › License terms in our example rate have an NPV of \$864,014 with a 30% discount
 - Licensor NPV is still \$115,922
- › Goal seek: set Licensor NPV = \$0 by varying running royalty rate
 - 5% → 6.4%
- › Or by increasing final milestone payment
 - \$500,000 → \$930,412

- › 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!

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

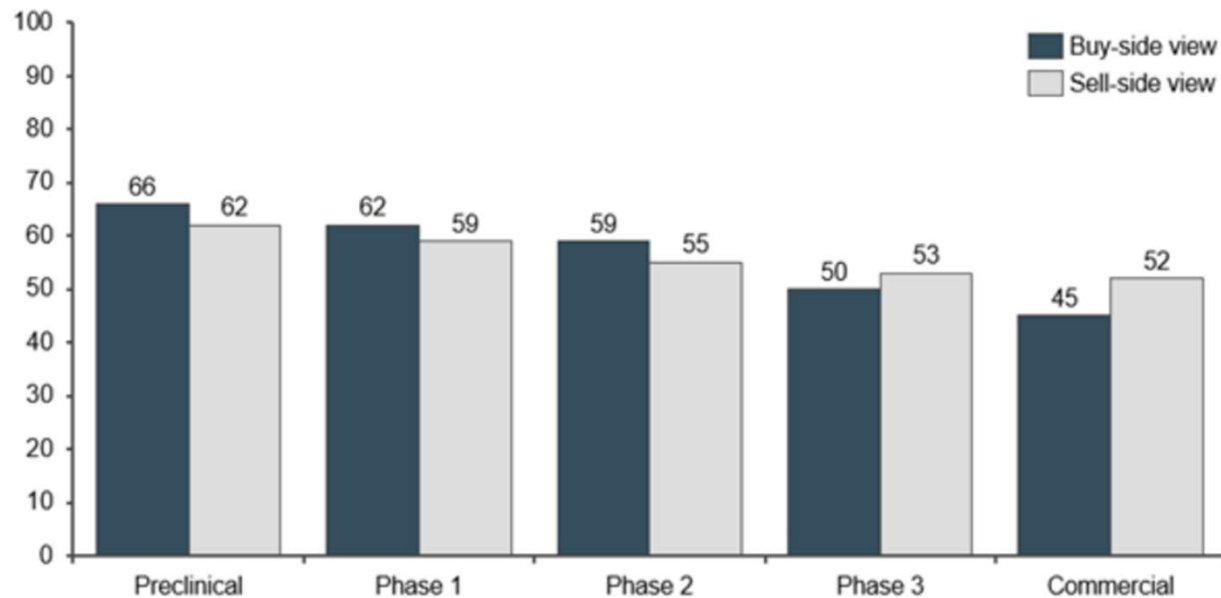
NPV Split Valuation

- ▶ Model 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 III 40%

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NPV Split Valuation

Average percent of total asset value going to buyers, by development stage
Phase of development



Source: L.E.K. HIC BD simulator survey (2020)

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Example

► In the example we looked at above:

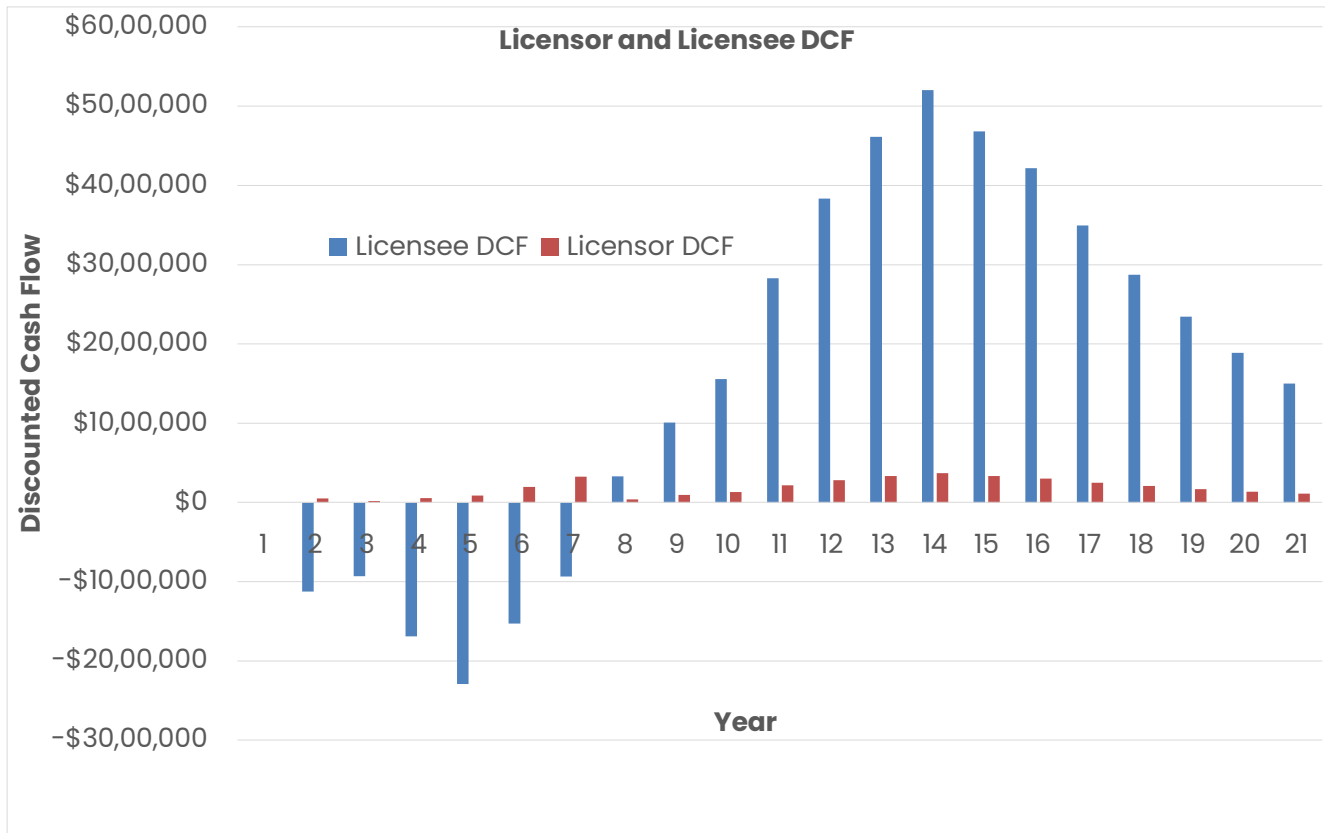
- 11% discount rate:
 - Project NPV = \$35.6 million
 - Licensee NPV = \$31.9 million
 - Licensor NPV = \$3.8 million

► NPV Split:

- Licensor 10.4%
- Licensee 89.6%

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		\$ (1,000,000)	\$ (1,000,000)	\$ (2,000,000)	\$ (3,000,000)	\$ (2,000,000)	\$ (1,000,000)	\$ (100,000)	\$ (100,000)	\$ (100,000)	\$ (200,000)
Product Cash Flow	\$ 164,304,000	\$ (1,075,000)	\$ (1,010,000)	\$ (2,012,000)	\$ (3,014,000)	\$ (2,020,000)	\$ (1,025,000)	\$ 690,000	\$ 2,290,000	\$ 3,890,000	\$ 7,790,000
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		\$ (1,075,000)	\$ (909,910)	\$ (1,632,984)	\$ (2,203,811)	\$ (1,330,637)	\$ (608,288)	\$ 368,902	\$ 1,102,998	\$ 1,687,974	\$ 3,045,304
NPV		\$ 35,595,998									

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)
\$ (300,000)	\$ (400,000)	\$ (500,000)	\$ (500,000)	\$ (500,000)	\$ (460,000)	\$ (420,000)	\$ (380,000)	\$ (340,000)	\$ (300,000)
\$ 11,690,000	\$ 15,590,000	\$ 19,490,000	\$ 19,490,000	\$ 19,490,000	\$ 17,930,000	\$ 16,370,000	\$ 14,810,000	\$ 13,250,000	\$ 11,690,000
0.35	0.32	0.29	0.26	0.23	0.21	0.19	0.17	0.15	0.14
\$ 4,117,037	\$ 4,946,447	\$ 5,571,038	\$ 5,018,953	\$ 4,521,579	\$ 3,747,448	\$ 3,082,343	\$ 2,512,259	\$ 2,024,894	\$ 1,609,452



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Example

- › What if licensee insists it won't go higher than a 7.5% NPV split?
- › Use Goal Seek:
 - Set Licensor NPV split = 7.5%
 - Vary running royalty rate
 - 3.1%

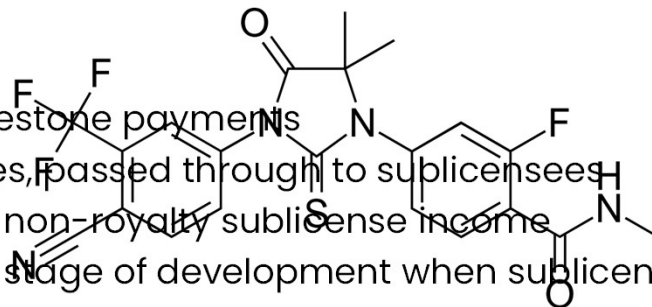
Late Stage Drug Deals

- ▶ 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
 - Probably delayed deal till first patient dosed!
 - \$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

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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

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
 - → CAGR 14.3%
- 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

Risk Adjusted NPV (raNPV)

- › Aka expected NPV or eNPV
- › In 1980's, risk was accounted for by unbelievably high discount rates
 - Resulted in negative NPV's for drug development projects
 - So economically rational business people wouldn't develop drugs
- › But they were developing them
 - So the model must be wrong
- › Data on success rates by clinical stage accounts for risk explicitly
 - First 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!)¹ this in 1996
 - Pre State Street Bank
- › Big pharma's develop both NPV's and raNPV for portfolio management

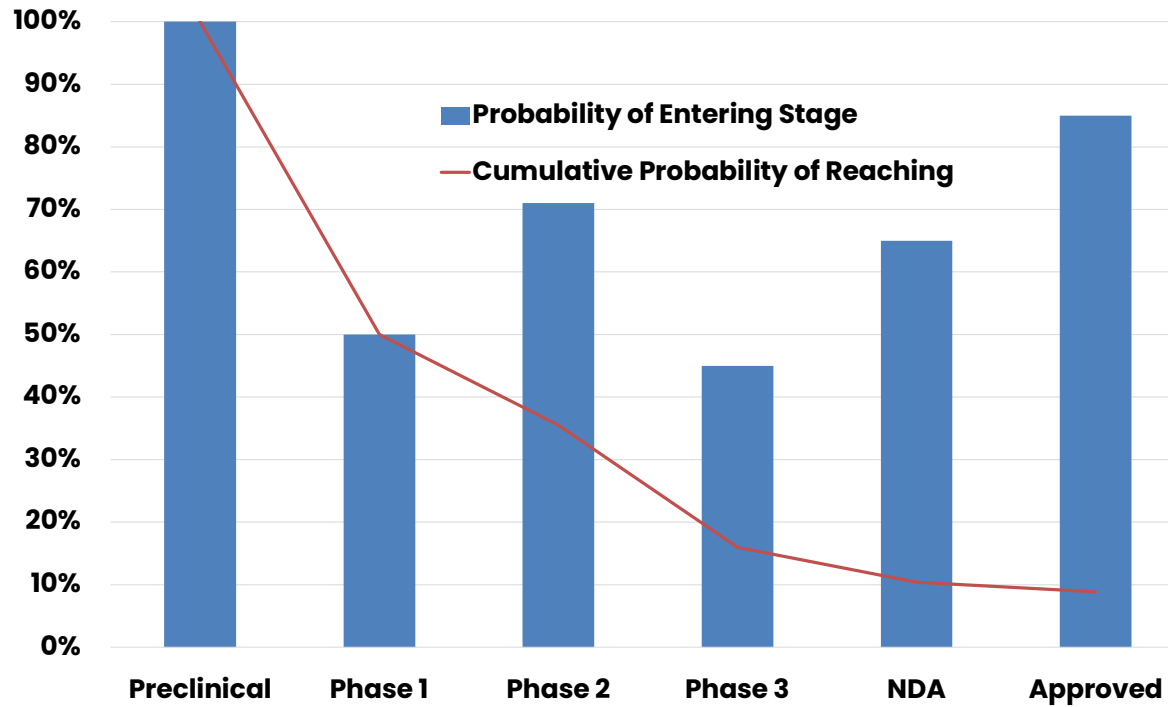
¹ "Risk Adjusted Net Present Value -- a New Approach to Valuing Early Stage Technologies", A. Stevens, *Journal of Biotechnology in Healthcare*, 2, 335-351, (Spring, 1996)

Stage Success Rates

	<u>DiMasi</u>					Median
NCE's	1995	2010	FDA	BIO	Takebe	
Preclinical			50.0%		25.7%	37.9%
Phase I	75.0%	71.0%	40.0%	61.3%	80.0%	71.0%
Phase II	48.0%	45.0%	45.0%	26.5%	47.6%	45.0%
Phase III	75.0%	64.0%	65.0%	48.7%	66.7%	65.0%
NDA	85.0%	93.0%	85.0%	78.0%	77.8%	85.0%

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Stage and Cumulative Success Rates



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raNPV Analysis of Our Example

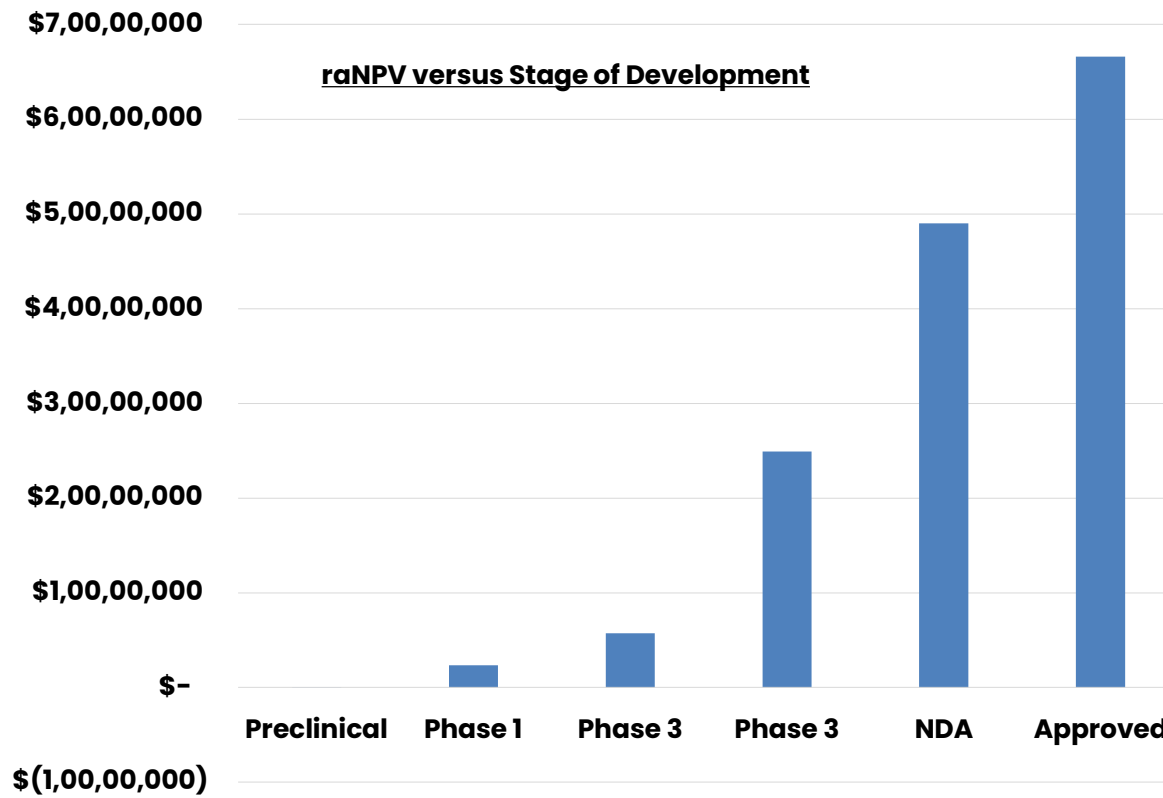
raNPV Analysis										
Year		1	2	3	4	5	6	7	8	9
Preclinical				Phase 1	Phase 2	Phase 3	NDA	Approved		
Cash Flow	\$ 164,304,000	\$ (1,075,000)	\$(1,010,000)	\$(2,012,000)	\$(3,014,000)	\$(2,020,000)	\$(1,025,000)	\$ 690,000	\$ 2,290,000	\$ 3,890,000
Prob of Success	1.00	1.00	0.50	0.71	0.45	0.65	0.85			
Cumulative PoS		1.00	1.00	0.50	0.36	0.16	0.10	0.09	0.09	0.09
ra Cash Flow	\$ 10,808,068	\$ (1,075,000)	\$(1,010,000)	\$(1,006,000)	\$(1,069,970)	\$ (322,695)	\$ (106,433)	\$ 60,901	\$ 202,120	\$ 343,339
Discount Factors	11%	1.00	0.90	0.81	0.73	0.66	0.59	0.53	0.48	0.43
raNPV Preclinical	\$ (32,750)	\$ (1,075,000)	\$ (909,910)	\$ (816,492)	\$ (782,353)	\$ (212,569)	\$ (63,163)	\$ 32,560	\$ 97,353	\$ 148,984

10	11	12	13	14	15	16	17	18	19	20
\$ 7,790,000	\$ 11,690,000	\$ 15,590,000	\$ 19,490,000	\$ 19,490,000	\$ 19,490,000	\$ 17,930,000	\$ 16,370,000	\$ 14,810,000	\$ 13,250,000	\$ 11,690,000
0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09	0.09
\$ 687,560	\$ 1,031,781	\$ 1,376,003	\$ 1,720,224	\$ 1,720,224	\$ 1,720,224	\$ 1,582,535	\$ 1,444,847	\$ 1,307,158	\$ 1,169,470	\$ 1,031,781
0.39	0.35	0.32	0.29	0.26	0.23	0.21	0.19	0.17	0.15	0.14
\$ 268,784	\$ 363,377	\$ 436,583	\$ 491,710	\$ 442,982	\$ 399,083	\$ 330,757	\$ 272,053	\$ 221,737	\$ 178,721	\$ 142,053

raNPV at Different Stages of Development

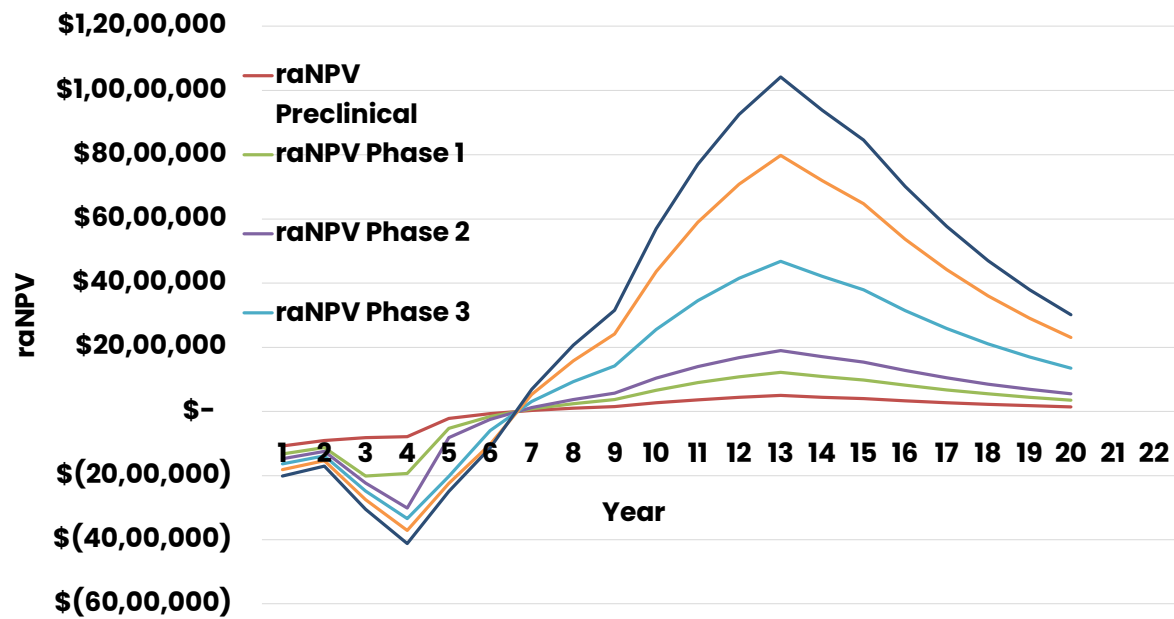
<u>Stage</u>	<u>raNPV</u>
Preclinical	\$ (32,750)
Phase 1	\$ 2,364,905
Phase 3	\$ 5,718,237
Phase 3	\$ 24,906,689
NDA	\$ 49,022,560
Approved	\$ 66,579,272

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raNPV at Different Stages of Development



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List Pricing

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

Getting Paid

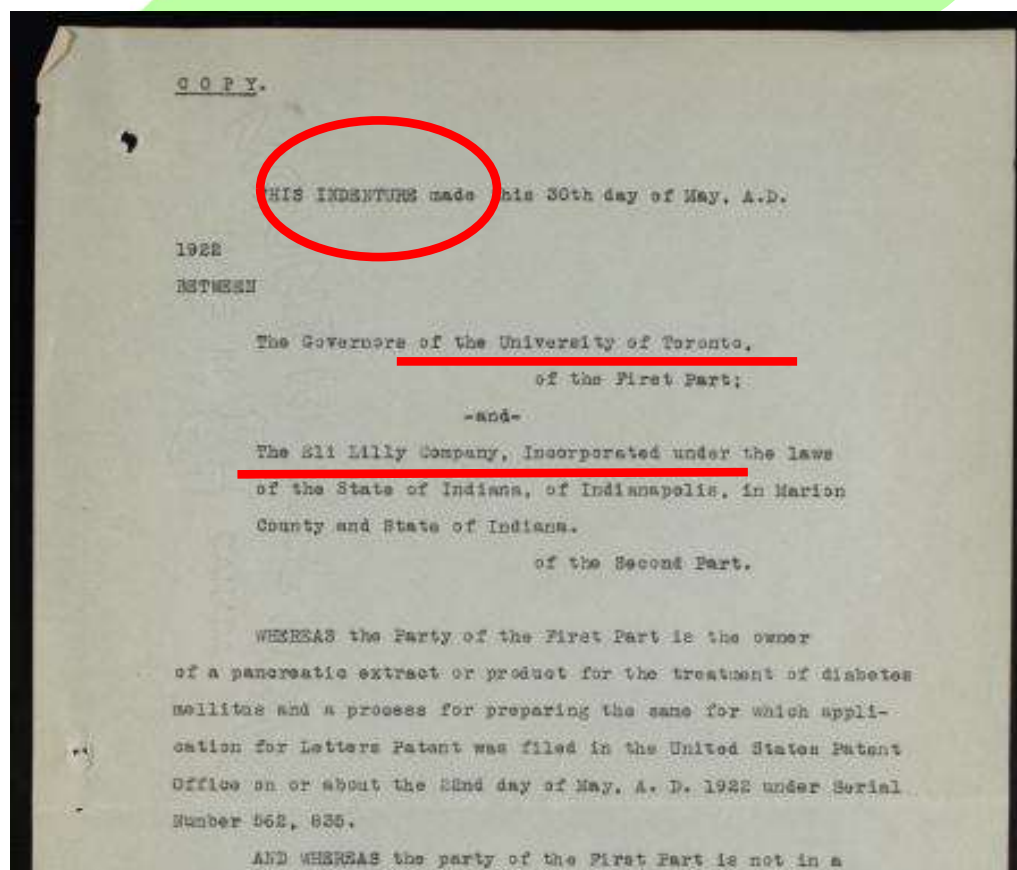
- › Important to have a good tracking system
 - Know when reports and payments are due
 - Follow-up the next day if not received
- › Trust but verify
 - Track licensee's progress
 - Website
 - Press releases
 - SEC filings
 - Google Alert
- › Tracking responsibility clearly defined in office
 - Licensing officer
 - Alliance manager
 - Large companies generally have a different person manage the alliance

Forecasting Income

- Leadership will want to know what income they can expect
 - One year forecast probably part of budget presentation
 - Should be able to forecast one year out with reasonable confidence
 - Ask licensees for sales forecasts for marketed products
 - Compare with public announcements
 - Wild card will be new product launches
 - Timing
 - Market success
 - The longer the forecast timeline the more uncertainty
 - Try to avoid firm forecasts
 - Talk about the pipeline
 - If you have to, probability-adjust numbers
 - Prepare for major patent expirations years in advance
 - Amazing how many Directors retire the year a major patent expires!

And if all else fails.....

5%



-4-

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.

(11) If the methods referred to in paragraph 10 are patentable

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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

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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

		<u>2017</u>	<u>2018</u>	<u>2019</u>	<u>2020</u>	<u>2021</u>	<u>2022</u>	<u>2023</u>
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%

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

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Discount

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

		<u>2017</u>	<u>2018</u>	<u>2019</u>	<u>2020</u>	<u>2021</u>	<u>2022</u>	<u>2023</u>
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Total								\$279.24

Reconciliation

- › NPV is \$279.24 million
 - Award was \$756 million
- › Use Goal Seek function
 - Set NPV to \$756 million
 - Vary Royalty Rate to get there

		<u>2017</u>	<u>2018</u>	<u>2019</u>	<u>2020</u>	<u>2021</u>	<u>2022</u>	<u>2023</u>
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
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astevens@bu.edu

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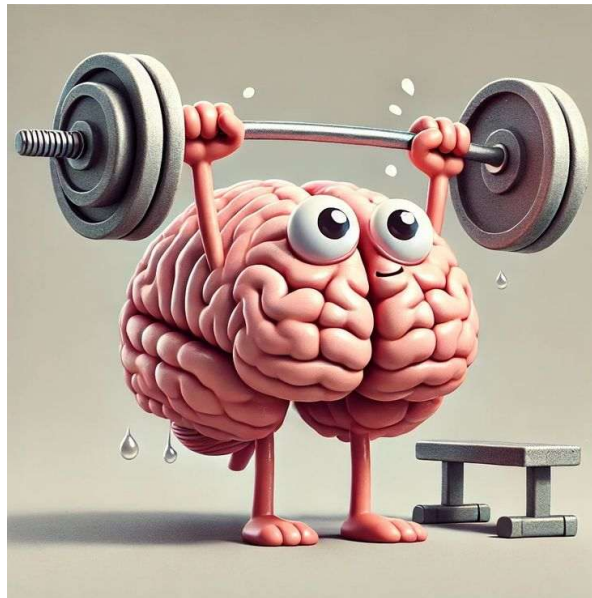
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Questions?

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Exercise coming up next



Time to put your neurons to work!

Exercise 3:

Valuation

Neha Jacob, Premnath V

Learning goals

This exercise is designed to teach the following:

- ☐ Provide an example of a valuation exercise
- ☐ Understand how it can be used and its limitations as well
- ☐ Understand what factors determine the valuation of a technology

Instructions

What is available to you:

- ☐ A Case
- ☐ An Excel sheet of a Cash Flow Discounting based Valuation

What you need to do:

- ☐ Understand the Excel Sheet
- ☐ Change parameters as suggested and see the consequence

Time plan:

- ☐ 10 min: Background
- ☐ 15 min: Understand the Excel Sheet
- ☐ 20 min: Change parameters and see what happens. List learnings

The Case: Outline

- › Technology: Low carbon process for production of a specialty chemical B
- › Patent scope: a) Catalyst C -- composition and process of making, b) Process for conversion of A→B using catalyst C
- › Patent coverage: US, EU, CN, IN; Likely to be granted; Patent life: 1 Jan 2023 – 31 Dec 2042
- › Value proposition of technology: a) 10% higher yield, b) Significant reduction in carbon emission
- › About Party 1: R&D Lab
- › About Party 2: Large Indian chemical company supplying B globally already. Majority market is the EU. Global market share is 15%. Has already invested 20m\$ in a plant 10 years ago. Makes a margin of 20%
- › Data points:
 - Global market for B: 500m\$; Market break up: 40% (USA), 30% (EU), 15% (CN), RoW (15%)
 - Market growth rate of 10% CAGR
 - Production of B: China (30%), India (30%), Saudi Arabia (20%), ROW (20%)
 - Price: 10\$/ kg; Price is increasing at 3% PA. Annual demand: 50,000 tons or 50 million kg
 - Technology is at TRL 4
 - Further development cost is 5 m\$ over next 12 months; Low because they have all scale up facilities available.
 - Cost of catalyst same as what is used currently

Value proposition for licensee

- ❑ The potential licensee already has a process.
- ❑ (Understanding motivation and projecting the path ahead) Why is the licensee interested in a license?
 - Higher product yield of 10% ?
 - Reduced barrier to enter EU ?
 - Reduced carbon tax for selling in EU ?
 - Say, carbon tax will reduce margins by 5% and market share by 3%
 - Pressure from India regulators to reduce carbon emissions ? How serious is the threat?
 - Pressure from shareholders to reduce carbon emissions ? How serious is the threat?
 - Keeping technology away from potential new entrants/ competitors
 - Any other reasons?
- ❑ How will you “discover” the motivations?

Thumb rules

- › Nothing sacrosanct about these rules, but this is what we will use for building the base case:
 - Technology share of profits ~ 25%
 - Upfront fee: 20% of NPV; Rest as Running Royalties

Understand the Excel Sheet

- We will now go through the Excel sheet: Link to Sheet

Parameter changes:

Change this parameter	Report what happens to: • Company valuation • Tech valuation
Market size: 100m\$, 500 m\$	
Market share of licensee: 5%, 15%	
Margin of licensee: 10%, 20%, 30%	
Development costs: 5m\$, 10m\$, 15m\$	

**Well done &
thanks for participating**



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INDUSTRIAL DEVELOPMENT ORGANIZATION



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