

# IP VALUATION PRACTICES IN RESEARCH INSTITUTIONS IN CUBA: CIM/CIMAB EXPERIENCES

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WIPO regional workshop on IP valuation for BioPharma Industry  
Havana, February 5th 2019

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# QUE ES UNA PATENTE?

- Una patente es el documento mediante el cual un inventor hace públicos sus inventos a cambio del derecho de excluir a otros de practicarlo.
- Por tanto, una patente es un derecho **NEGATIVO** o de exclusión.
- El titular o licenciatarario de una patente adquiere el derecho a excluir a otros de usar, hacer, vender, ofertar para la venta o importar la invención patentada.
- **UNA PATENTE ES UN ACTIVO!!!!**

Number of Patents

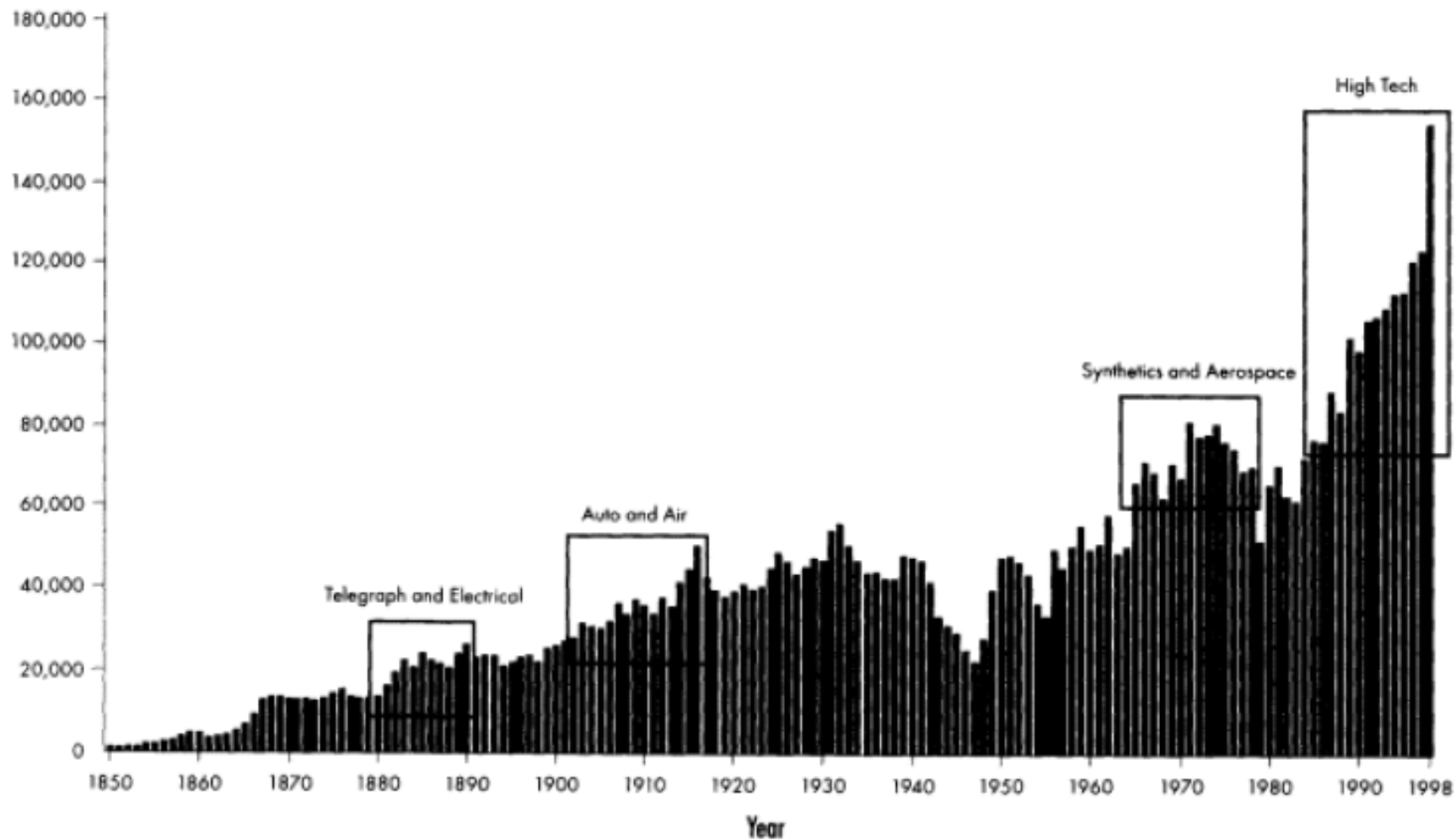
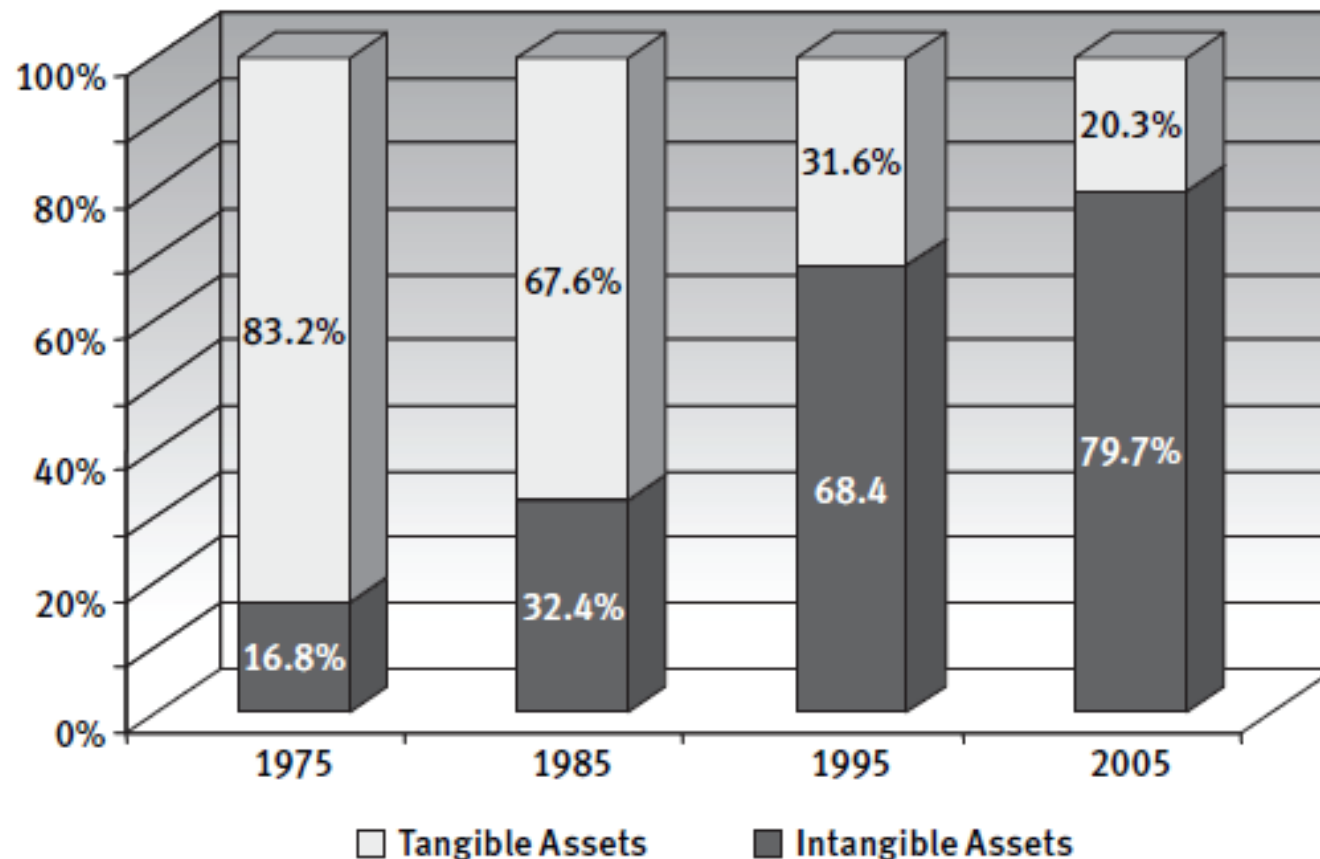


FIGURE 6.1

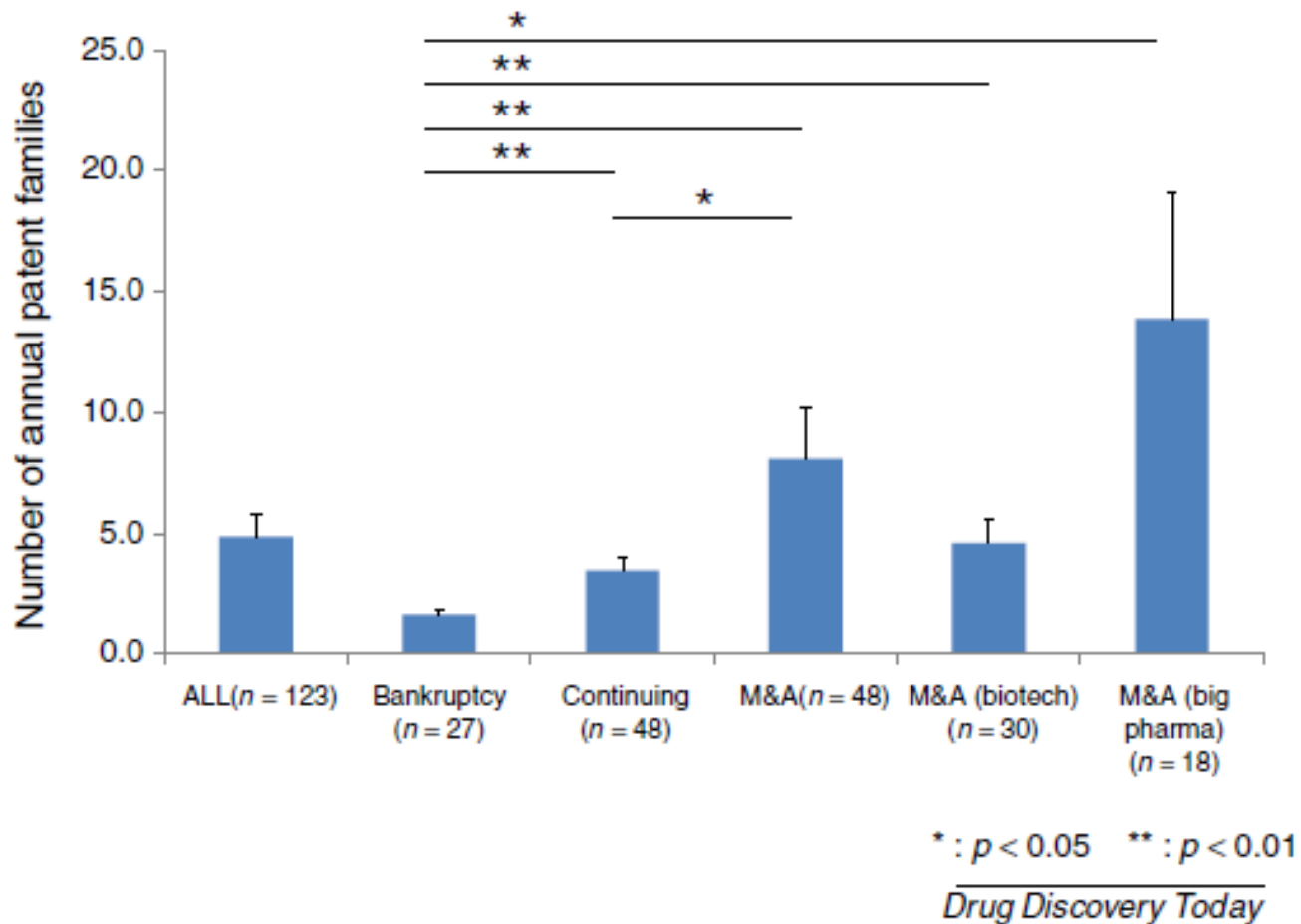
## COMPONENTS OF S&amp;P 500 MARKET VALUE

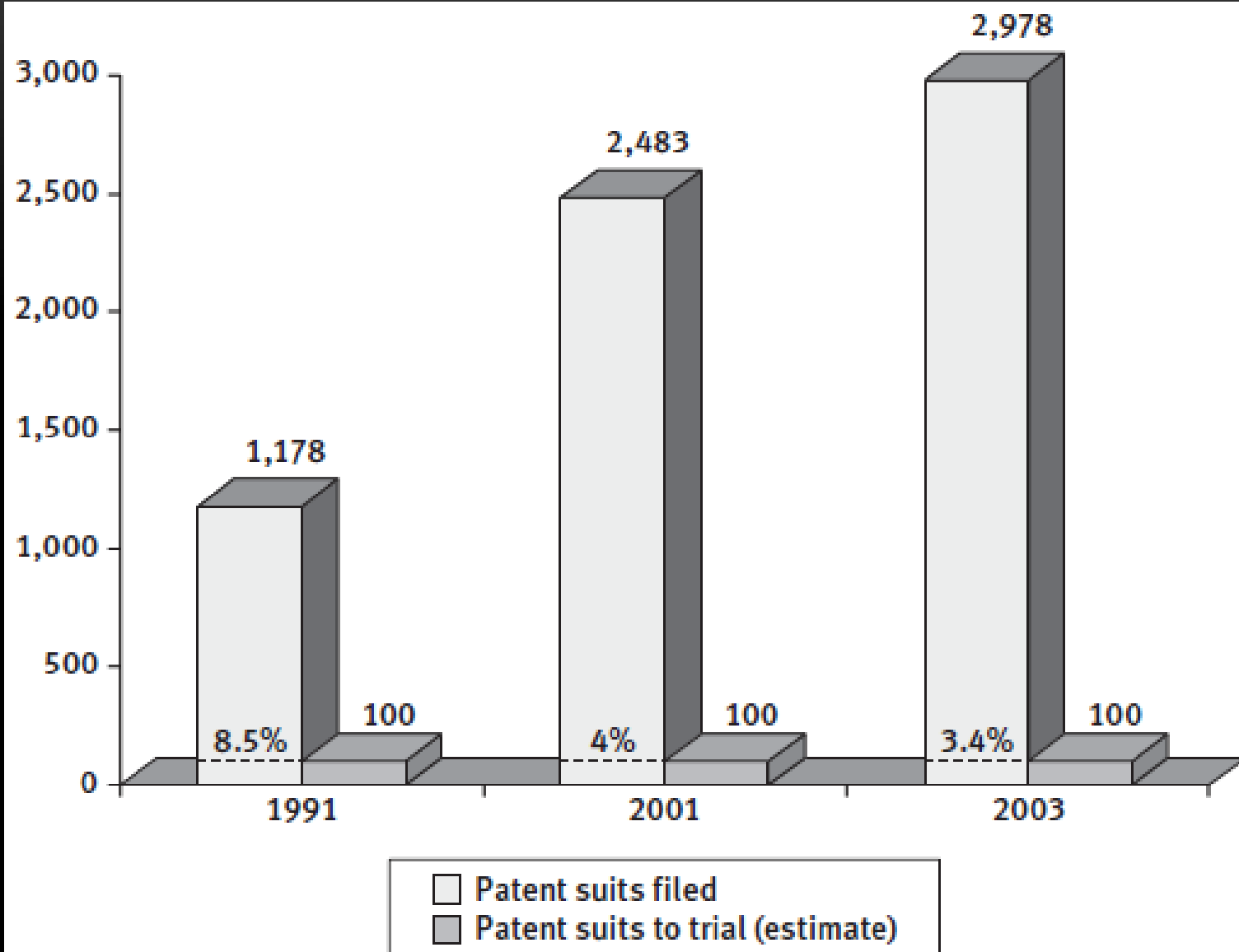


Source: Brookings Institution, Ocean Tomo

**IP Value.** Even with a correction for the stock market bubble, 80% of the market value of companies in the S&P 500 are comprised of intangible assets, mostly intellectual property.

# LA FORTALEZA DE LA CARTERA DE PATENTES CORRELACIONA CON EL ÉXITO DE LA EMPRESA BIOTECNOLÓGICA?





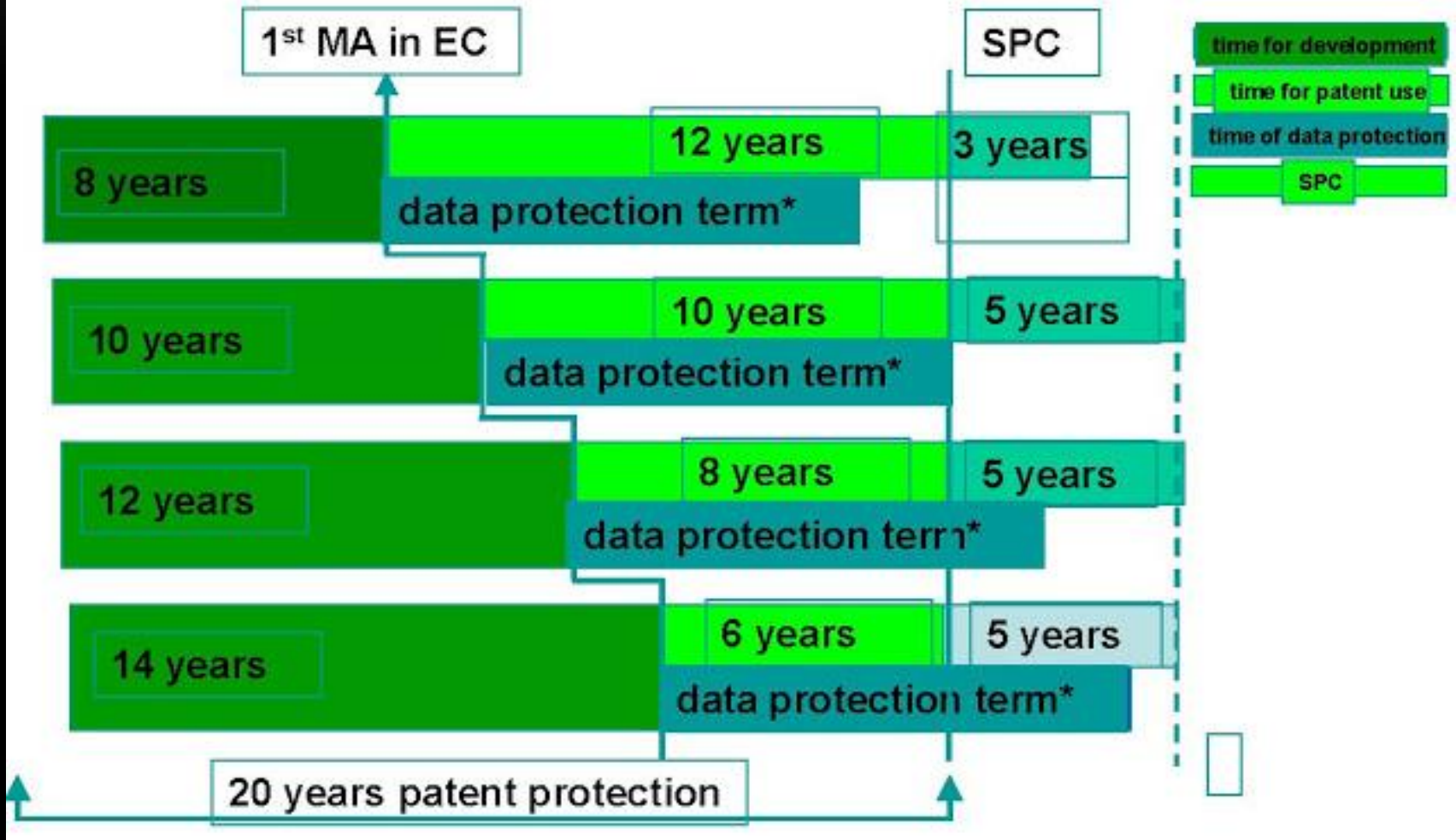
Source: © Brody Berman Associates, Inc.

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PATENT EXPIRATION IS NOT THE SOLE  
DETERMINANT OF MARKET EXCLUSIVITY

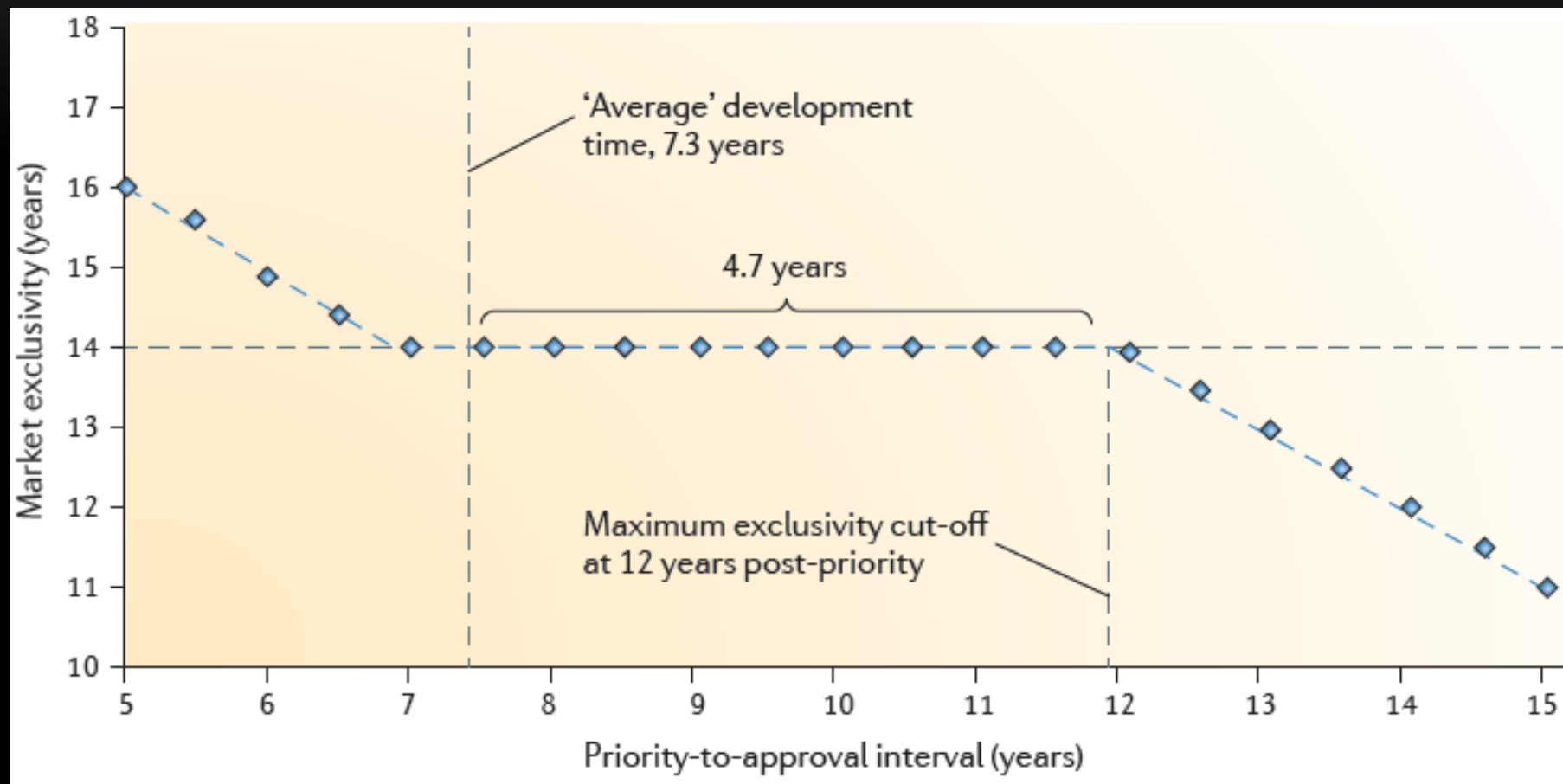
# Market exclusivity in Europa

## Supplementary Protection Certificate





# Market exclusivity in the USA



# CUERPO LEGAL QUE REGULA LA GESTIÓN DE LAS PATENTES Y LA EXCLUSIVIDAD DEL MERCADO FARMACÉUTICO EN EEUU.

| Cuerpo legal                                    | Año  | Observaciones   |
|---|------|---|
| The Patent Act                                  | 1790 | 1er estatuto sobre patentes en EEUU.  |
| The Bayh-Dole Act                               | 1980 | Permitió la negociación de patentes generadas por Universidades e Institutos con fondos provenientes del gobierno.  |
| The Orphan Drug Act                             | 1983 | Creó una designación especial para drogas dirigidas a enfermedades huérfanas (< 200 000 casos anuales). Estableció un período de 7 años de exclusividad de mercado. |
| The Hatch-Waxman Act                            | 1984 | Facilitó la entrada al mercado de los productos genéricos y estableció los “Patent Term Restoration”  |
| Best Pharmaceutical for Children Act            | 1997 | Otorga 6 meses adicionales de exclusividad de mercado a productos de uso pediátrico.  |
| Biologics Price Competition and Innovation Act  | 2010 | Facilitó la entrada de los Biosimilares y estableció 12 años de exclusividad para productos Biológicos innovadores.   |
| Generating Antibiotic Incentives Now (GAIN) Act | 2012 | Otorga 5 años de exclusividad adicional a productos eficaces contra Infecciones “resistentes”.  |

# ***How to manage patents businesswise?***

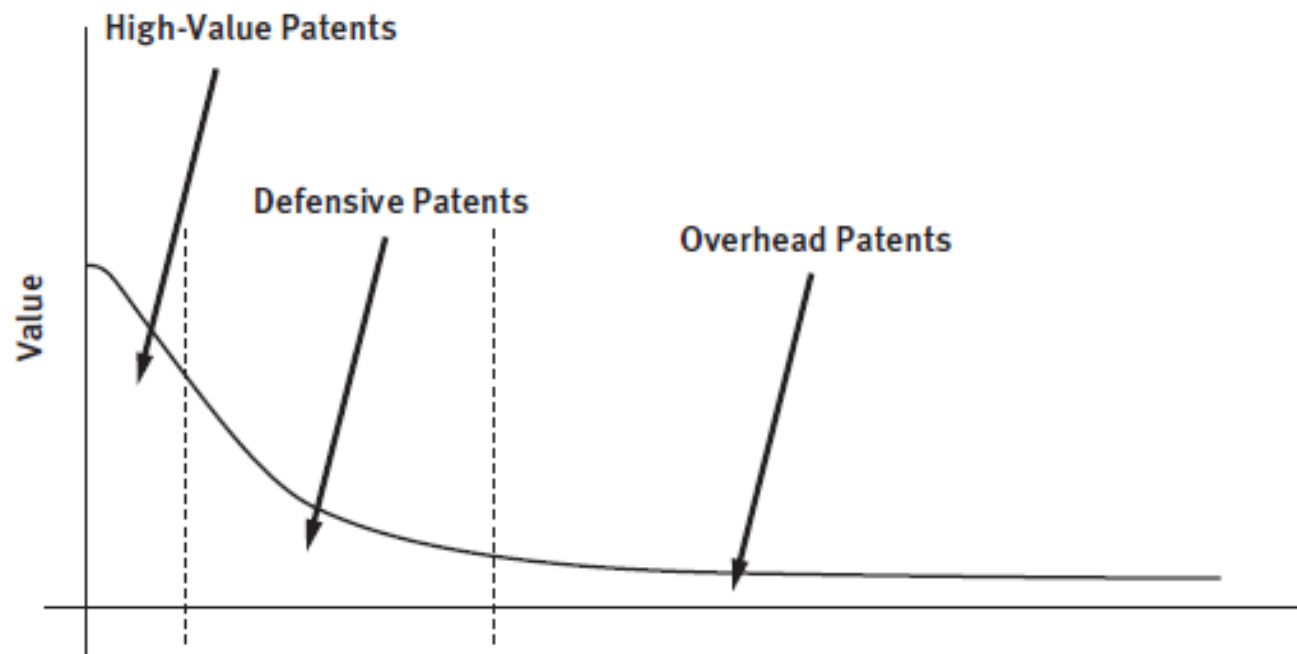
**FIGURE 5.1**    **TYPICAL U.S. PATENT COSTS**

|   |          |
|---|----------|
| Prepare Original Application                      | \$10,000 |
| Response to USPTO Office Action                   | \$ 2,500 |
| USPTO Filing Fees                                 | \$ 5,000 |
| Total Cost to Obtain Patent (filing & legal fees) | \$17,500 |
| Patent Maintenance Fees (3, 7, 11 yrs)            | \$ 7,000 |

The above costs do not include R&D expenditures. Costs are similar or higher (with translations) in other key filing areas, such as Japan.

# “NOT ALL PATENTS ARE CREATED EQUAL”

FIGURE 5.2

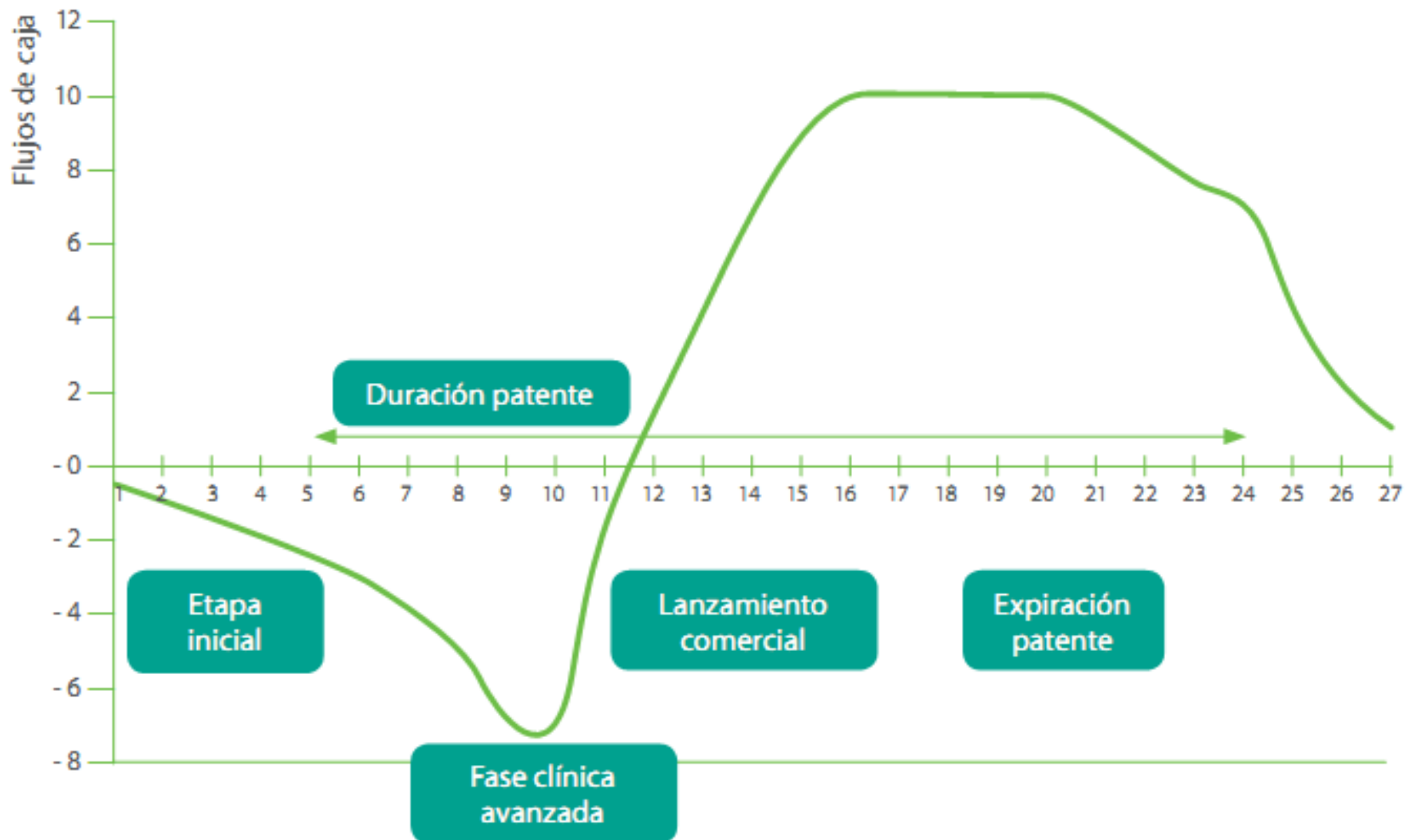


**Anatomy of an IT Portfolio.** Fewer than 5% of most significant patent portfolios in high-tech have direct value. Some 45%–50% of patents are necessary to maintain for defensive strategy and future growth. But fully 50% or more of patents are unrelated to current activities and serve no productive purpose.

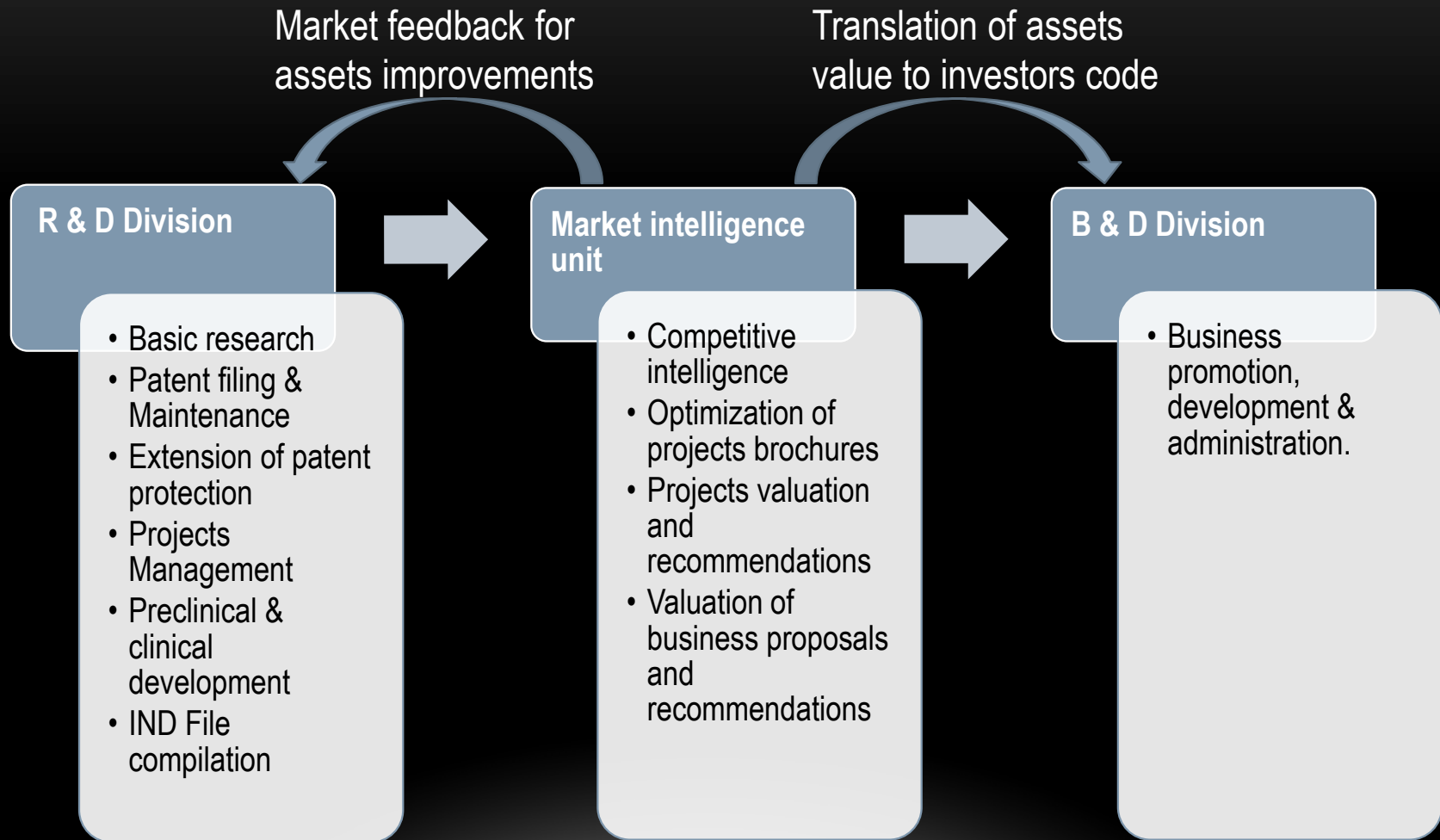
# **CIM PROCEDURE FOR BUDGET ALLOCATION TO PATENT FILING & MAINTENANCE EXPENSES: PRIORITIZATION BY MARKETS & TIMEFRAME**

| <b>Patent registration</b> | <b>After 5 years</b>   | <b>After 10 years</b>  | <b>After 15 years</b>  |
|----------------------------|------------------------|------------------------|------------------------|
| Territories Priority 1     | Territories Priority 1 | Territories Priority 1 | Territories Priority 1 |
| Territories Priority 2     | Territories Priority 2 | Territories Priority 2 | Abandoned              |
| Territories Priority 3     | Territories Priority 3 | Abandoned              |                        |
| Territories Priority 4     | Abandoned              |                        |                        |

# PRODUCT LIFECICLE

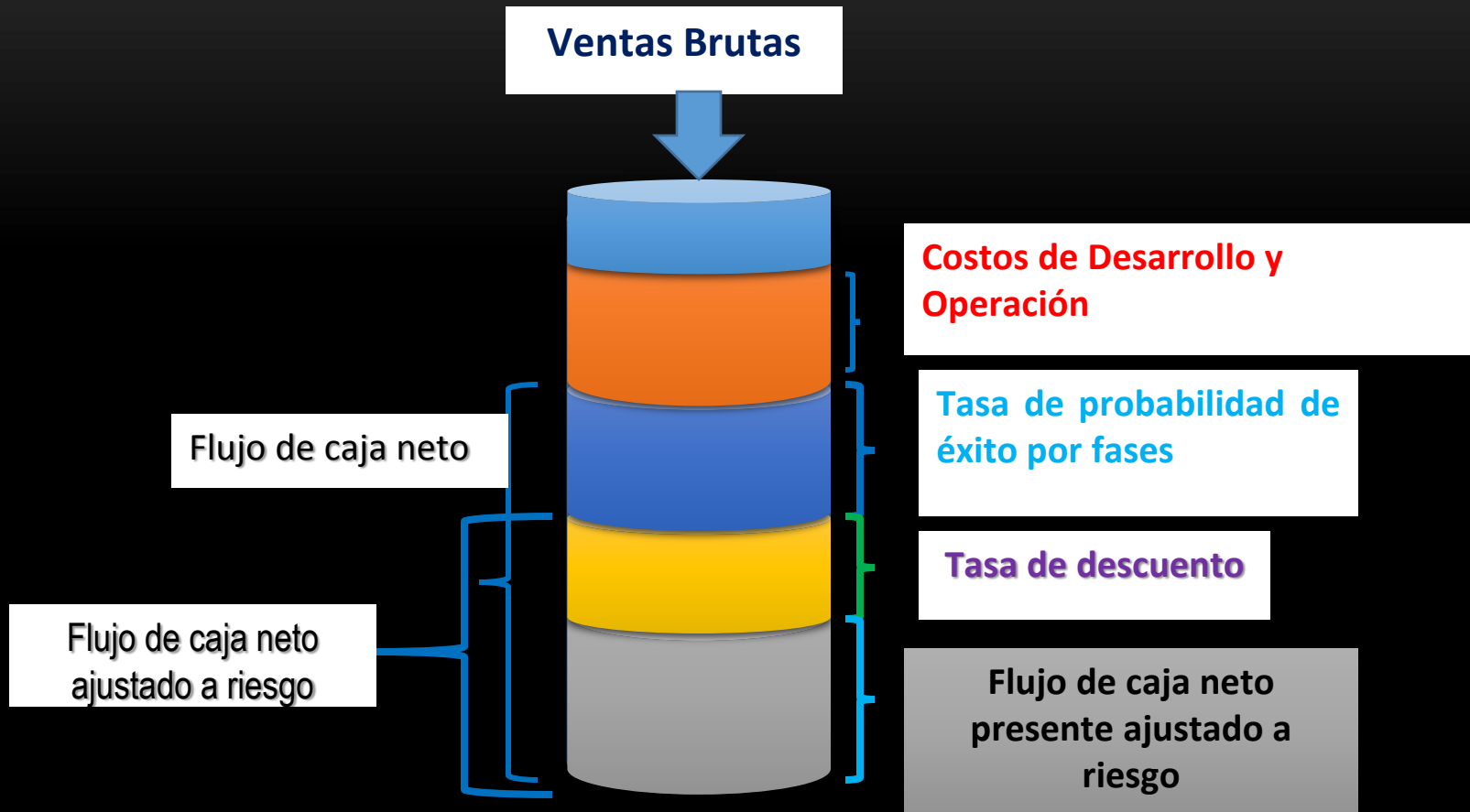


# IP VALUATION MANAGEMENT AT CIM





# Método de Flujo de Caja Descontado

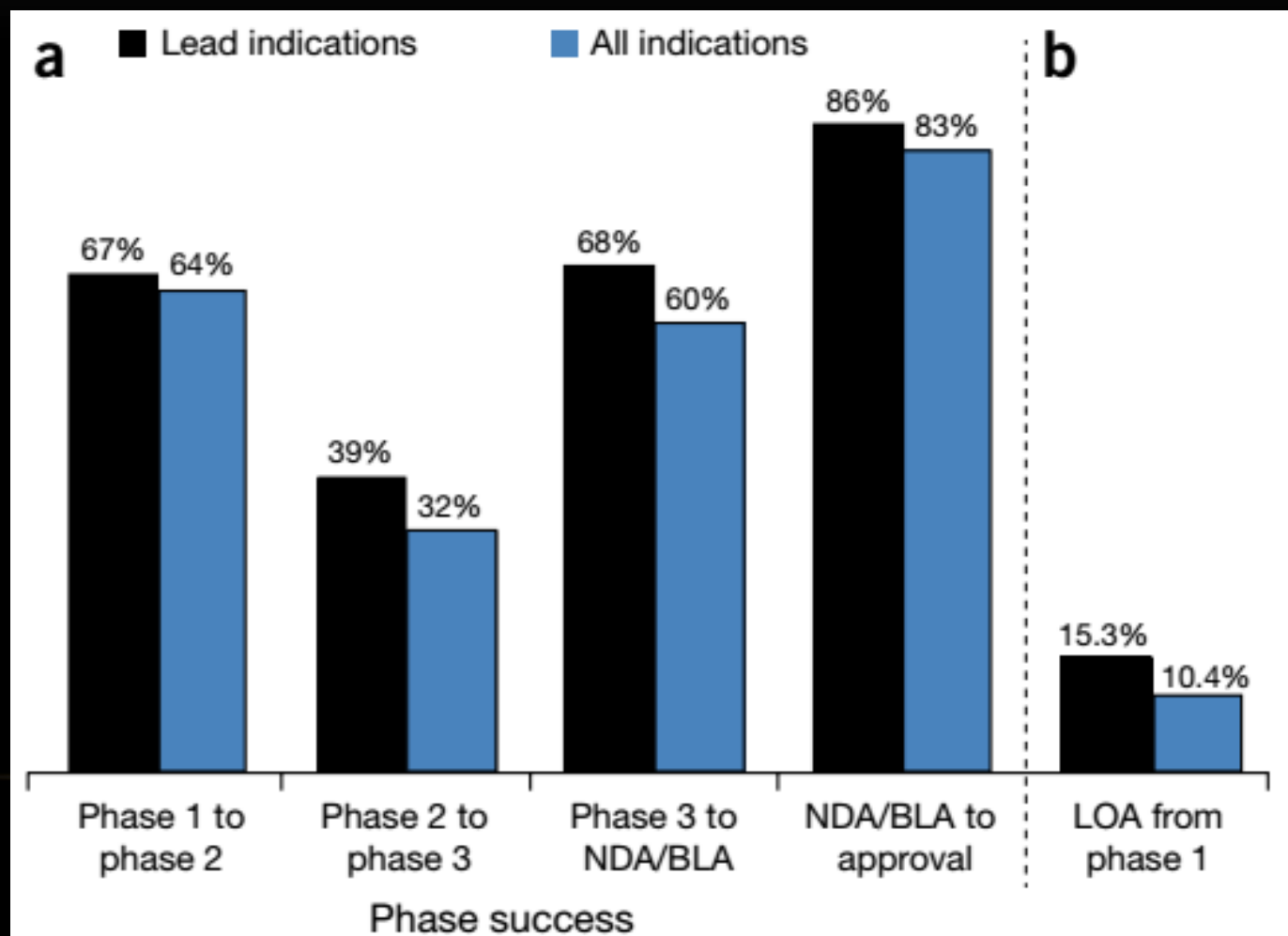


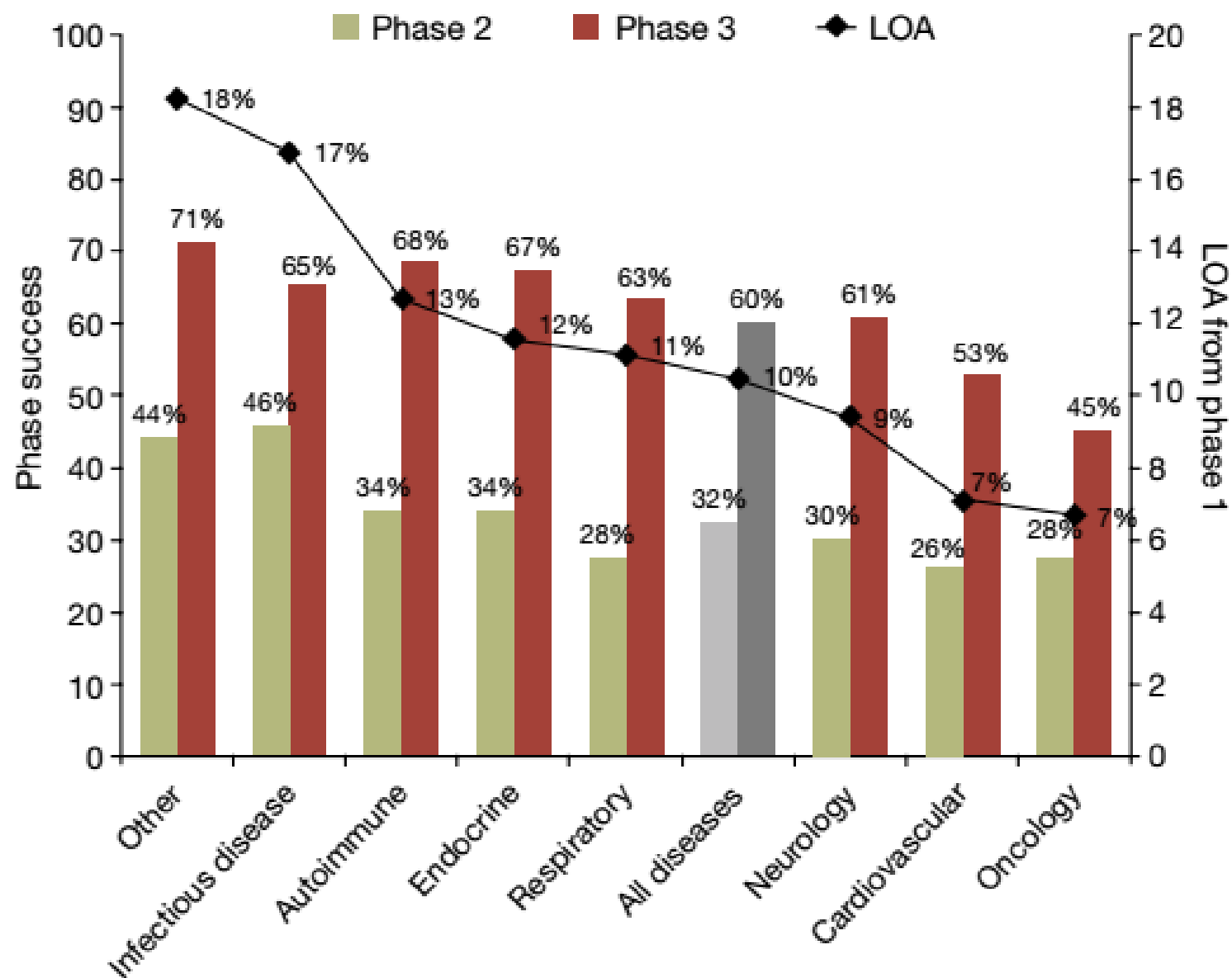
$$rNPV = \sum_{t=1}^p \text{Cylinder}_t$$

# Clinical development success rates for investigational drugs

Michael Hay, David W Thomas, John L Craighead, Celia Economides & Jesse Rosenthal

VOLUME 32 NUMBER 1 JANUARY 2014 NATURE BIOTECHNOLOGY





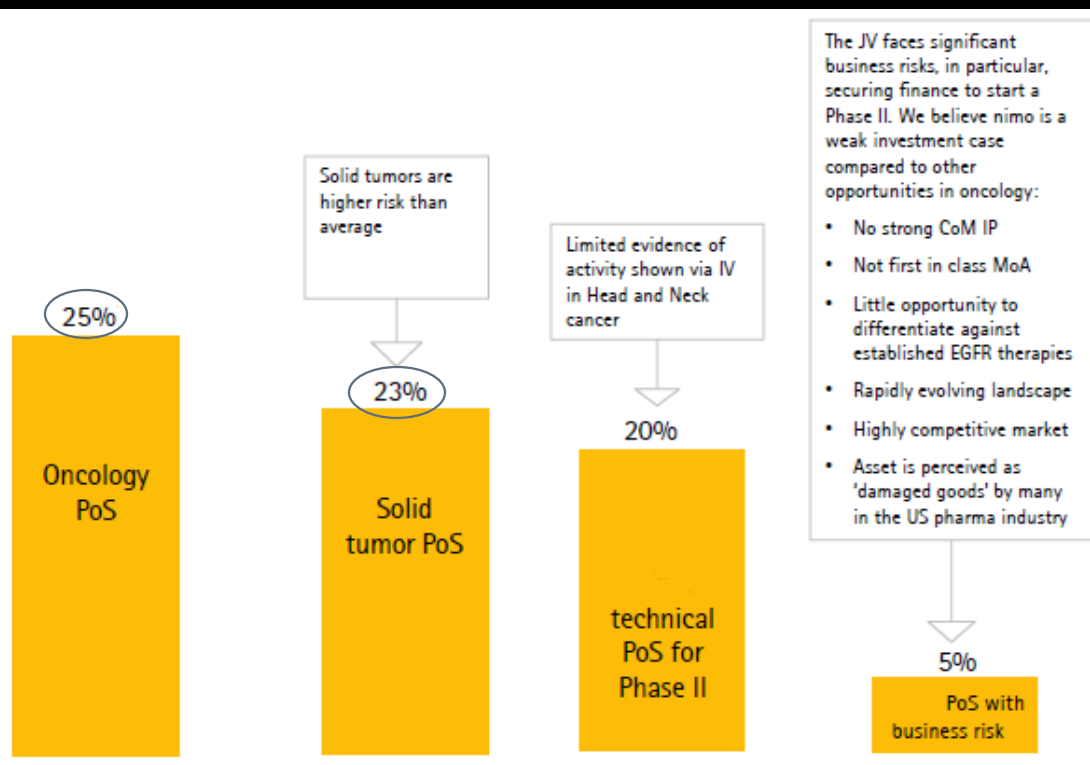
**Table 7 Phase success and LOA for oncology subgroups and cancer types**

|                                     | Phase 1 to phase 2          |                                    |                            |                        | Phase 2 to phase 3          |                                    |                            |                        | Phase 3 to NDA/BLA          |                                    |                            |                        | NDA/BLA to approval         |                                    |                            |                        |
|-------------------------------------|-----------------------------|------------------------------------|----------------------------|------------------------|-----------------------------|------------------------------------|----------------------------|------------------------|-----------------------------|------------------------------------|----------------------------|------------------------|-----------------------------|------------------------------------|----------------------------|------------------------|
|                                     | Total in phase <sup>a</sup> | Advanced or suspended <sup>b</sup> | Phase success <sup>c</sup> | Phase LOA <sup>d</sup> | Total in phase <sup>a</sup> | Advanced or suspended <sup>b</sup> | Phase success <sup>c</sup> | Phase LOA <sup>d</sup> | Total in phase <sup>a</sup> | Advanced or suspended <sup>b</sup> | Phase success <sup>c</sup> | Phase LOA <sup>d</sup> | Total in phase <sup>a</sup> | Advanced or suspended <sup>b</sup> | Phase success <sup>c</sup> | Phase LOA <sup>d</sup> |
| All indications                     | 2,541                       | 1,918                              | 64.5%                      | 10.4%                  | 3743                        | 2268                               | 32.4%                      | 16.2%                  | 1554                        | 975                                | 60.1%                      | 50.0%                  | 908                         | 659                                | 83.2%                      | 83.2%                  |
| Total oncology                      | 919                         | 651                                | 63.9%                      | 5.4%                   | 1451                        | 827                                | 28.3%                      | 8.5%                   | 383                         | 147                                | 36.7%                      | 30.0%                  | 142                         | 104                                | 81.7%                      | 81.7%                  |
| Total solid tumors                  | 668                         | 483                                | 66.7%                      | 5.7%                   | 1114                        | 636                                | 26.3%                      | 8.6%                   | 299                         | 172                                | 41.3%                      | 32.7%                  | 88                          | 67                                 | 79.1%                      | 79.1%                  |
| Renal cell cancer (RCC)             | 20                          | 15                                 | 86.7%                      | 18.4%                  | 54                          | 33                                 | 30.3%                      | 21.2%                  | 15                          | 10                                 | 70.0%                      | 70.0%                  | 7                           | 6                                  | 100.0%                     | 100.0%                 |
| Head and neck cancer                | 6                           | 5                                  | 100.0%                     | 14.3%                  | 23                          | 12                                 | 50.0%                      | 14.3%                  | 14                          | 7                                  | 42.9%                      | 28.6%                  | 3                           | 3                                  | 66.7%                      | 66.7%                  |
| Hepatocellular (liver) cancer (HCC) | 18                          | 15                                 | 73.3%                      | 6.6%                   | 39                          | 25                                 | 36.0%                      | 9.0%                   | 12                          | 4                                  | 25.0%                      | 25.0%                  | 1                           | 1                                  | 100.0%                     | 100.0%                 |
| Breast cancer                       | 54                          | 47                                 | 68.1%                      | 5.7%                   | 119                         | 61                                 | 21.3%                      | 8.4%                   | 34                          | 25                                 | 56.0%                      | 39.2%                  | 14                          | 10                                 | 70.0%                      | 70.0%                  |
| Non-small cell lung cancer (NSCLC)  | 63                          | 55                                 | 87.3%                      | 5.7%                   | 161                         | 94                                 | 29.8%                      | 6.5%                   | 46                          | 23                                 | 26.1%                      | 21.7%                  | 11                          | 6                                  | 83.3%                      | 83.3%                  |
| Prostate cancer                     | 42                          | 8                                  | 71.0%                      | 5.6%                   | 103                         | 24                                 | 20.9%                      | 7.8%                   | 25                          | 8                                  | 56.3%                      | 37.5%                  | 11                          | 3                                  | 66.7%                      | 66.7%                  |
| Colorectal cancer (CRC)             | 45                          | 37                                 | 62.2%                      | 5.1%                   | 87                          | 56                                 | 21.4%                      | 8.2%                   | 18                          | 13                                 | 38.5%                      | 38.5%                  | 4                           | 4                                  | 100.0%                     | 100.0%                 |
| Ovarian cancer                      | 31                          | 25                                 | 68.0%                      | 4.6%                   | 72                          | 37                                 | 27.0%                      | 6.8%                   | 15                          | 8                                  | 25.0%                      | 25.0%                  | 3                           | 1                                  | 100.0%                     | 100.0%                 |
| Pancreatic cancer                   | 29                          | 24                                 | 75.0%                      | 2.3%                   | 66                          | 36                                 | 30.6%                      | 3.1%                   | 19                          | 10                                 | 20.0%                      | 10.0%                  | 2                           | 2                                  | 50.0%                      | 50.0%                  |
| Total hematological tumors          | 216                         | 152                                | 58.6%                      | 9.9%                   | 317                         | 179                                | 34.6%                      | 16.9%                  | 78                          | 45                                 | 55.6%                      | 48.8%                  | 48                          | 33                                 | 87.9%                      | 87.9%                  |
| Multiple myeloma (MM)               | 43                          | 29                                 | 69.0%                      | 9.7%                   | 48                          | 30                                 | 23.3%                      | 14.0%                  | 13                          | 5                                  | 60.0%                      | 60.0%                  | 5                           | 4                                  | 100.0%                     | 100.0%                 |
| Non-Hodgkin's lymphoma (NHL)        | 38                          | 28                                 | 57.1%                      | 8.5%                   | 62                          | 35                                 | 40.0%                      | 14.8%                  | 19                          | 9                                  | 44.4%                      | 37.0%                  | 8                           | 6                                  | 83.3%                      | 83.3%                  |
| Chronic lymphocytic leukemia (CLL)  | 17                          | 12                                 | 50.0%                      | 7.3%                   | 41                          | 24                                 | 29.2%                      | 14.6%                  | 10                          | 8                                  | 62.5%                      | 50.0%                  | 7                           | 5                                  | 80.0%                      | 80.0%                  |
| Myelodysplastic syndrome (MDS)      | 12                          | 7                                  | 71.4%                      | 4.8%                   | 22                          | 9                                  | 33.3%                      | 6.7%                   | 6                           | 5                                  | 20.0%                      | 20.0%                  | 4                           | 3                                  | 100.0%                     | 100.0%                 |

<sup>a</sup>Number of indications identified. <sup>b</sup>Total number of transitions used to calculate the success rate, the *n* value noted in the text. The difference between "Total in phase" and "Advanced or suspended" is the number of indications that remain in development. <sup>c</sup>Probability of successfully advancing to the next phase. <sup>d</sup>Probability of FDA approval for drugs in this phase of development.

# INVESTORS RISK PERCEPTIONS GOES BEYOND HISTORIC BENCHMARKS

| Historic PoS benchmarks from the literature       |                    |            |              |               |            |
|---|--------------------|------------|--------------|---------------|------------|
| Source  | Category           | Phase I-II | Phase II-III | Phase III-BLA | BLA-Market |
| BIO- Clinical Dev Success rates 2006-2015         | Overall oncology   | 62.8%      | 24.6%        | 40.1%         | 82.4%      |
|   | Solid tumors       | 64.1%      | 23%          | 34.2%         | 79.6%      |
|   | Overall Biologics  | 66%        | 34.4%        | 57.2%         | 88.4%      |
|   | Biomarker directed | 76.7%      | 46.7%        | 76.5%         | 94.5%      |
| Hay, M. et al, <i>Nature Biotechnology</i> , 2014 | Overall oncology   | 63.9%      | 28.3%        | 45.2%         | 81.7%      |
|   | Solid tumors       | 66.7%      | 26.3%        | 41.3%         | 79.1%      |
|   | Oncology biologics | 61.6%      | 30.6%        | 43.9%         | 88.9%      |
|   | Oncology vaccines  | 50%        | 39.5%        | 8.3%          | 100%       |



# INVESTORS RISK PERCEPCION GOES BEYOND HISTORIC SUCCESS RATES

| Category           | Comment  |
|--------------------|--|
| Financing risk     | The vast majority of life science investors need to see strong IP protection. The lack of broad composition of matter IP around several of the products significantly increases the hurdle to raise development capital.   |
| Manufacturing risk | We understand the joint venture will be building new manufacturing facilities in Cuba. From the data we have seen to date, there is a gap between the quality standards deployed in Cuba vs current FDA requirements. Bridging this gap will require a fundamental change in personnel mindset. Additionally, securing FDA approval for importation of Phase III and commercial drug product maybe challenging for a Cuban facility. |
| Recruitment risk   | We believe the joint venture may find it difficult to attract the right people. Execution of a complex clinical development plan requires skilled and experienced staff and managers. Given the recent investment in oncology, companies of all sizes are finding it to attract and retain high-caliber staff.   |
| Political risk     | It is uncertain if the US administration will continue to encourage strong business relations between US and Cuba. In addition, it is not certain whether the OFAC license will be renewed. On the other hand, it is unlikely the White House will block effective drugs and the US administration is aiming to make drug approval faster and easier.  |