1. Overview of product valuation
2. rNPV product valuation
3. Company valuation
4. Deal structure
5. Case study
Mission

Independent assessment and valuation of technology driven companies / products in growth industries

Information services / Life Sciences Databases
Biotechgate.com

- Experts Finance / High-tech industries
- Not a venture capitalist
- International experience
- Track record of over 250 valued companies
- Clients such as NVF, Fraunhofer Gesellschaft, European Investment Bank; VCs; Arpida/Evolva
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Valuation of a product

- Licensing deal
- Strategic development decision
- Expenses included are only those relevant to the product
- Product not industry comparables required
- Management risks not taken into account
Introduction

Input

• Development cost and timelines
• Production / Marketing cost
• Market / expected sales
• Success rate based on historical data

Output

• Expected annual discounted cash flows
Valuation components

- Determine timelines and cash flows in each phase
- Develop solid assumptions for all key variables
1. Development phase => investment
   Product Risk (r) => success rate

2. Market phase => revenues
   Patent expiry => end of revenues
   (often no terminal value)

3. Discount => non-specific risk (General Risk)
Risk-adjusted NPV

Risk adjusted Net Present Value

• Also called eNPV
• Method of choice for Big Pharma

Benefits:
• Helps understand accurate value and maximises deal options
• Adjusts value for Development Risk and Discount rate

⇒ Risk is split in two components
  1) Product Risk (attrition rate)
  2) General Risk (discount rate)
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Five Step Process

1. Determine Cash Flows in Development Phase

2. Determine Cash Flows in Market Phase

3. Discount with Discount rate

4. Adjust for Risk

5. Sum cash flows
rNPV – Example

- Phase 1, single product company
- 20% discount rate
- 11% Probability of success (p1 to market)

⇒ CF: USD 2’269m
⇒ DCF: USD 127m
⇒ rNPV: USD 8m
Development Phase

1. Determine cost and duration of clinical trials
   - Geographic location
   - Number of patients and centres
   - Type of treatment

2. Manufacturing
   - Regulatory affairs
   - Long term animal tox. studies
   - Misc. administration

3. Discount rate
4. Risk
5. Overiew

www.venturevaluation.com
## Example Trial Inputs

<table>
<thead>
<tr>
<th>In US$ 000's</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time (Years)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Number of Patients</td>
<td>~10</td>
<td>~200</td>
<td>~3000</td>
<td></td>
</tr>
<tr>
<td>Cost per patient</td>
<td>7</td>
<td>7</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Total Patient costs</td>
<td>70</td>
<td>1400</td>
<td>21000</td>
<td></td>
</tr>
<tr>
<td>Total patient costs as percentage of total costs*</td>
<td>30%</td>
<td>30%</td>
<td>30%</td>
<td></td>
</tr>
<tr>
<td>Total non-patient costs</td>
<td>163</td>
<td>3267</td>
<td>49000</td>
<td></td>
</tr>
<tr>
<td>Total costs</td>
<td>233</td>
<td>4667</td>
<td>70000</td>
<td>2500</td>
</tr>
<tr>
<td>Total Development Costs (unadjusted)</td>
<td></td>
<td></td>
<td></td>
<td>77400</td>
</tr>
</tbody>
</table>

* To factor in other cost including animal studies, manufacturing, administration etc.
Cost and Lead Times

1. Development

2. Market

3. Discount rate

4. Risk

5. Cost

Representative Development and Regulatory Review Time Profile (synthesis to approval)

- **Synthesis – Approval**: 128.0 months
- **Clinical Start – Approval**: 96.8 months
- **Synthesis – Phase I**: 31.2 months
- **Phase I – II**: 19.8 months
- **Phase II – III**: 30.3 months
- **Phase III – NDA/BLA Submission**: 30.7 months
- **NDA/BLA Submission – Approval**: 16.0 months

Source: Tufts Center, 2014

Source: Business Insights
Develop assumptions to predict the future market

Methods used:

- Bottom-up approach
  - Based on primary market data

- Top-down approach
  - Based on comparable products
A. Define Growth Phase (4-8 years)
B. Define Mature Phase (1-4 years)
C. Define Decay Phase (7-10 years)
Which variables affect the Life Cycle?

1. Me-too drug or a pioneer
2. Competitive landscape
3. Physician response
4. Ease of reaching physicians
5. Need for physician training
6. Payor reimbursement
7. Pharmacoeconomic reimbursement
**Bottom up approach**

**Primary Market Research**

**Physicians:**
- What are the unmet medical needs
- What are the attitudes towards current therapies

**Patients:**
- How do the patients view the current treatments

**Product:**
- What therapeutic position is the drug likely to achieve
  - (1st line, 2nd line; EU, US)
  - Develop a pricing model

**Product life cycle** and **Market share** are obtained from top-down methods or industry accepted values.
**Sales Forecast**

<table>
<thead>
<tr>
<th>Western EU</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population (000's)</td>
<td>300'000</td>
<td>306'000</td>
</tr>
<tr>
<td>Incidence rate (%)</td>
<td>0.020%</td>
<td>0.020%</td>
</tr>
<tr>
<td>Diagnosed population</td>
<td>60'000</td>
<td>61'200</td>
</tr>
<tr>
<td>Population treated with drugs</td>
<td>42'000</td>
<td>42'480</td>
</tr>
<tr>
<td>Compliance rate</td>
<td>80%</td>
<td>80%</td>
</tr>
<tr>
<td>Addressable population</td>
<td>30'240</td>
<td>30'845</td>
</tr>
<tr>
<td>Market penetration rate (%)</td>
<td>18%</td>
<td>34%</td>
</tr>
<tr>
<td>Patient population</td>
<td>5'443</td>
<td>10'487</td>
</tr>
<tr>
<td>Market share</td>
<td>12%</td>
<td>12%</td>
</tr>
<tr>
<td>Price (EUR)</td>
<td>2000</td>
<td>2000</td>
</tr>
<tr>
<td>Sales Western EU (EUR 000's)</td>
<td>1'306</td>
<td>2'517</td>
</tr>
<tr>
<td>USA Sales</td>
<td>2'540</td>
<td>4'798</td>
</tr>
<tr>
<td>Japan Sales</td>
<td>392</td>
<td>755</td>
</tr>
<tr>
<td>Rest of the World (RoW) Sales</td>
<td>1'270</td>
<td>2'399</td>
</tr>
<tr>
<td>Total sales (EUR 000's)</td>
<td>5'508</td>
<td>10'469</td>
</tr>
</tbody>
</table>

**Peak Sales Value**

- USD 1bn => USD 8m
- USD 0.7bn => USD 3m
- USD 2bn => USD 25m
Used discount rate in rNPV:

- Early stage 12% - 28%
- Mid stage 10% - 22%
- Late stage 9% - 20%

Source: www.biostrat.dk

Cost of equity and non-development associated risks:

20% => USD 8m
25% => USD 2m
15% => USD 21m
Adjust for risk (I)

Source: Nature Biotechnology; Clinical development success rates for investigational drugs; January 2014
LOA: Likelihood of approval
Adjust for risk (II)

Source: Nature Biotechnology; Clinical development success rates for investigational drugs; January 2014
Adjust for Risk (III)

The relation between Risk and Value

- Completion of a phase → Direct value increase

Cumulative Success rate: 11%

Value

m USD

<table>
<thead>
<tr>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>NDA/BLA</th>
<th>Approval/Market</th>
</tr>
</thead>
<tbody>
<tr>
<td>64%</td>
<td>32%</td>
<td>61%</td>
<td>86%</td>
<td></td>
</tr>
<tr>
<td>672</td>
<td>477</td>
<td>125</td>
<td>18</td>
<td>8</td>
</tr>
</tbody>
</table>

DISCOUNT RATE

- 1 Devel.
- 2 Market
- 3 Discount rate
- 4 Risk
- 5 $$ $$ $$ $$
### Sum Cash Flows

- Sum discounted, risk-adjusted yearly cash flows to a single value

<table>
<thead>
<tr>
<th>YEAR</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase</td>
<td>P III</td>
<td>Approval</td>
<td>Market</td>
<td>Market</td>
<td>Market</td>
</tr>
<tr>
<td>DEVELOPMENT COSTS</td>
<td>-50'000</td>
<td>-2'500</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SALES</td>
<td></td>
<td></td>
<td>50'000</td>
<td>100'000</td>
<td>250'000</td>
</tr>
<tr>
<td>-Discounts, Returns, Allowances</td>
<td>0%</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>NET REVENUES (USD 000’s)</td>
<td>-</td>
<td>-</td>
<td>50'000</td>
<td>100'000</td>
<td>250'000</td>
</tr>
<tr>
<td>Total Product Costs</td>
<td>-50'000</td>
<td>-2'500</td>
<td>40'000</td>
<td>80'000</td>
<td>300'000</td>
</tr>
<tr>
<td>EBIT</td>
<td>-50'000</td>
<td>-2'500</td>
<td>40'000</td>
<td>80'000</td>
<td>300'000</td>
</tr>
<tr>
<td>Tax</td>
<td>0%</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>FREE CASH FLOW</td>
<td>-43'478</td>
<td>-1'890</td>
<td>26'301</td>
<td>45'740</td>
<td>149'153</td>
</tr>
<tr>
<td>DISCOUNTED CASH FLOWS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage</td>
<td>Phase III</td>
<td>Approval</td>
<td>Market</td>
<td>Market</td>
<td></td>
</tr>
<tr>
<td>Cumulative sucess rate*</td>
<td>100%</td>
<td>75%</td>
<td>66%</td>
<td>66%</td>
<td></td>
</tr>
<tr>
<td>RISK ADJUSTED CASH FLOWS</td>
<td>-43'478</td>
<td>-1'418</td>
<td>17'359</td>
<td>30'188</td>
<td>98'441</td>
</tr>
<tr>
<td>TOTAL PRODUCT VALUE</td>
<td>125'548</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Success rate

<table>
<thead>
<tr>
<th>Per phase</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cumulative</td>
<td>100%</td>
<td>100%</td>
<td>75%</td>
<td>66%</td>
</tr>
</tbody>
</table>
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Example

Early stage company
Sum-of parts valuation
Total value of project
Summary

- Use **Independent** and **unbiased** models
- Provide **simple** and **clear** valuations to understand costs, risks and revenues
- Product valuations **help to understand** investment, risk and return
- The value of the product has to be **shared** between licensee and licensor.
AIM: to develop a **fair** deal structure

- Product value has to be shared
- The licensee (Pharma) is compensated for taking on risk
- The licensor (Biotech) receives payments and shares some of the risk and rewards
- The model inputs and assumptions are simple, understandable, and transparent

The rNPV valuation can help to understand the deal terms
Deal structuring process

1. Determine Product Value

2. Determine handover time point

3. Determine preferred Milestones and Royalties

4. Negotiate terms
### Timing of payments

- Front/ back-loading a deal can heavily influence deal structure
- Deal terms dependent on needs of both parties

<table>
<thead>
<tr>
<th>Stage</th>
<th>In USD m</th>
<th>Payment of</th>
<th>rNPV* (or up-front)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up-front</td>
<td>1 m</td>
<td>1 m</td>
<td></td>
</tr>
<tr>
<td>Finish Pre-clinical</td>
<td>1 m</td>
<td>0.44 m</td>
<td></td>
</tr>
<tr>
<td>Finish Phase I</td>
<td>1 m</td>
<td>70’000</td>
<td></td>
</tr>
<tr>
<td>Finish Phase II</td>
<td>1 m</td>
<td>17’000</td>
<td></td>
</tr>
<tr>
<td>Finish Phase III</td>
<td>1 m</td>
<td>8’000</td>
<td></td>
</tr>
<tr>
<td>Approval / Enter market</td>
<td>1 m</td>
<td>5’000</td>
<td></td>
</tr>
<tr>
<td>Royalties</td>
<td>1%</td>
<td>0.70 m</td>
<td></td>
</tr>
</tbody>
</table>

* Time value of money and Risk adjusted
Timing of payments (II)

- Two very different deal structures can look identical
  - Non-discounted, non-risk adjusted

1. • 25 million upfront
   • 300 million milestones
   • 5% royalties

2. • 5 million upfront
   • 50 million milestones
   • 12% royalties
Conclusion

- Valuation is key in the development of biotechs
- Traditional methods are unsuited
- Value = future risk & potential
- Valuation is not an exact science
- Its all about the assumptions
1) Case study reading time
2) Group work
3) Presentation and wrap up

A) Determine the current value of XC-71F.

B) Would you accept the deal terms suggested by the biotech company?

C) Develop a deal scenario that is fair for both parties.

D) Present the results in a short presentation, justifying all major assumptions.
THE VALUATION EXPERTS

Thank you for listening!

Tel: +41 43 321 86 60
www.venturevaluation.com
a.peire@venturevaluation.com

Venture Valuation AG
Kasernenstrasse 11
8004 Zürich