VALUATIONLAB
FINANCIAL ANALYSIS

BASILEA PHARMACEUTICA

FOCUS AREA: SEVERE BACTERIAL AND FUNGAL INFECTIONS			
KEY DATA			SIX: BSLN
MARKET CAPITALIZATION (CHF MN)	508	**SHARE PRICE ON 26 APRIL 2023**	43
ENTERPRISE VALUE (CHF MN)	305	**RISK-ADJUSTED NPV PER SHARE** (CHF)	76
CASH AND INVESTMENTS (31 DECEMBER 2022) (CHF MN)	109	**UPSIDE/DOWNSIDE** (%)	80%
MONTHLY OPERATING EXPENSE (CHF MN)	9.0	**RISK PROFILE**	MEDIUM
CASH REACH (YEAR)	SUSTAINABLE	**SUCCESS PROBABILITY LEAD PIPELINE PROJECT**	80%
BREAK-EVEN (YEAR)	2022	**EMPLOYEES**	141
FOUNDED (YEAR)	2000	**LISTED** (YEAR)	2004
KEY PRODUCTS:	**STATUS**	**MAJOR SHAREHOLDERS:**	**(%)**
- CRESEMBA (INVASIVE FUNGAL INFECTIONS)	LAUNCHED	- BLACK CREEK / CI INVESTMENTS	4.9
- ZEVTERA (BACTERIAL LUNG INFECTIONS)	LAUNCHED (EU/ROW)	- CREDIT SUISSE FUNDS AG	3.3
- ZEVTERA (SAB*, ABSSSI** & CABP***)	US FILING Q3 2023	- JP MORGAN CHASE & CO	3.1
- DXR INHIBITOR PROGRAM (RESISTANT GRAM-NEGATIVE BACTERIA)	PRECLINICAL	- EXECUTIVE MANAGEMENT	0.0
		- FREE FLOAT	**100**
		- AVERAGE DAILY VOLUME (3 MONTHS)	3'697
UPCOMING CATALYSTS:	**DATE**	**ANALYST(S):**	BOB POOLER
- ZEVTERA: US FILING FOR SAB*, ABSSSI** AND CABP***	Q3 2023		BP@VALUATIONLAB.COM
- ZEVTERA (CONTRACTING A US COMMERCIALIZATION PARTNER)	BEFORE Q2 2024		+41 79 652 67 68
- ZEVTERA (US APPROVAL ASSUMING PRIORITY REVIEW)	Q2 2024		

* SAB = STAPHYLOCOCCUS AUREUS BACTEREMIA; ** ABSSSI = ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS; *** CABP = COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA

ESTIMATES AS OF 26 APRIL 2023

SOURCE: VALUATIONLAB ESTIMATES, BASILEA PHARMACEUTICA

Return to anti-infectives and profits

Net profit to at least triple in 2023, slight US Zevtera delay

Basilea is focused on the research and development of innovative treatments for severe bacterial and fungal infections that address the challenge of increasing resistance and non-response to current treatments, which are often associated with high mortality rates. The aim is to become a leading company in anti-infectives. Basilea has almost completed its exit from oncology through strategic transactions and partnerships. Two of Basilea's anti-infectives have been launched: 1) Zevtera (lung infections), launched in Europe in 2015 with Advanz responsible for commercialization since 2017, among others, and 2) Cresemba (invasive mold infections), launched in the US by partner Astellas in 2015, and in Europe in 2016 with Pfizer responsible for commercialization in Europe (ex-Nordics) since 2017 and in APAC since early 2018. Both products provide positive cash flows in launched markets thanks to extensive partnering and distribution agreements. Substantial upside should come from the upcoming US partnering and launch of Zevtera in the lucrative US market. Basilea has sufficient funds to finance its development plans and remain profitable for the foreseeable future. Our sum-of-parts risk-adjusted NPV (rNPV) amounts to CHF 76/share with a Medium Risk, risk profile.

Key catalysts:

1) **US NDA filing of Zevtera for severe bacterial infections (Q3 2023):** including bacteremia, skin infections, and lung infections; approval in the lucrative US market could occur around the Q2 2024, assuming Priority Review based on QIDP status.
2) **US commercialization partner for Zevtera (before Q2 2024):** expected to be contracted before its launch in mid 2024 in return for significant upfront, regulatory, and sales milestones and royalties on net sales in the lucrative US market.
3) **US approval of Zevtera for severe bacterial infections (Q2 2024):** assuming Priority Review based on granted QIDP designation. Our rNPV for Zevtera increases to CHF 4/share with a 100% (approved) success rate.

Recent developments

Below is an overview of the latest developments since our last Basilea Valuation Report was issued in January 2023.

April 26 – AGM – All proposals accepted by shareholders
At the Annual General Meeting (AGM), shareholders approved all board proposals, including the approval of the Annual Report, Financial Statements, and consolidated Financial Statements for the financial year 2022, the appropriation of the results, the discharge of the members of the Board of Directors and the Management Committee, the maximum compensation for the Board of Directors and the Management Committee, and amendments to the articles of association (to meet the requirements of the revision of the Swiss corporate law and reflect the move to Allschwil), the introduction of a capital band including conditional capital based on the capital band, and the election of the independent proxy and auditor. Domenico Scala was re-elected as Chairman of the Board. Dr. Carole Sable was elected as a new Board member. The existing Board members, Leonard Kruimer, Dr. Martin Nicklasson, Dr. Nicole Onetto, and Dr. Thomas Werner, were re-elected.

April 18 – US filing Zevtera delayed by 3-6 months and now planned for Q3 2023
The New Drug Application (NDA) submission for US approval of Zevtera in Staphylococcus aureus bacteremia (SAB), acute bacterial skin and skin structure infections (ABSSSI), and community-acquired bacterial pneumonia (CABP) has been pushed back to Q3 2023. Although Basilea has compiled the NDA dossier and is ready to make a submission to the FDA, after completion of FDA inspection readiness preparations, it became clear that the quality systems of one of their contract manufacturing organizations (CMOs) needed to be adapted prior to an FDA inspection. Basilea estimates that an additional three to six months of preparatory work will be needed to ensure the CMO is ready for FDA inspection, a prerequisite for an NDA review. The regulatory decision is now expected in Q2 2024 (previously at the end of 2023). The updated timelines for the Zevtera NDA submission do not have an impact on the FY 2023 guidance. Based on the Qualified Infectious Disease Product (QIDP) status, Zevtera will enjoy 10-year market exclusivity from the day of US approval and therefore has little impact on the positive investment case for Basilea.

March 23 – CHF 5 mn Japanese launch milestone received from Asahi Kasei
Partner Asahi Kasei achieved a milestone related to the launch of Cresemba in Japan, which triggered a CHF 5 milestone payment to Basilea. Japanese approval was already received in December 2022. Japan represents approximately 4% of global sales of newer antifungals.

February 14 – FY 2022 revenues exceed guidance – 2023 net profit to at least triple
Basilea reported FY 2022 results that exceeded guidance, underlining the continued strong performance of especially its hospital antifungal Cresemba. An operating profit of CHF 18.5 mn was reported (guidance: operating loss of between CHF 10-15 mn), resulting in a net profit of CHF 12.1 mn for the period. This marks the company's return to sustainable earnings from now onwards. Basilea guides net profit to at least triple in 2023.

STRATEGY - On track to become a leading & profitable anti-infectives company
Basilea has delivered on its strategic decision to exit oncology in 2022 and focus exclusively on anti-infectives. The company entered into three separate oncology

transactions (see Appendix, page 41) structured to provide significant proceeds, including upfront and near-term milestone payments (approximately CHF 2.5 mn is due in 2023). Basilea will share in the long-term value creation of these products. In 2023, the company will not incur material costs related to oncology activities and will retain the option to explore partnering opportunities for lisavanbulin. The company focuses on building a balanced R&D portfolio of antibacterial and antifungal drug candidates through internal and external research to support sustainable long-term growth beyond Cresemba and Zevtera with the strategic goal of becoming a leading anti-infectives company.

BASILEA RESULTS AND GUIDANCE IN A NUTSHELL

(IN CHF MN)	FY 2023 GUIDANCE	FY 2022 GUIDANCE	FY 2022	FY 2021	% CHANGE
+ PRODUCT REVENUE	-	-	32.7	26.2	25%
+ CONTRACT REVENUE	-	-	89.6	105.2	-15%
+ REVENUE FROM R&D SERVICES	-	-	0.0	0.2	-100%
+ OTHER REVENUE (E.G., BARDA, ONCOLOGY TRANSACTIONS)	-	-	25.5	16.6	54%
TOTAL REVENUE:	**155 - 158**	**116 -122**	**147.8**	**148.1**	0%
OF WHICH CRESEMBA & ZEVTERA RELATED REVENUE	145 - 148	98 - 104	122.3	131.4	-7%
OF WHICH ROYALTY INCOME	~74	~59	65.0	53.2	22%
- COST OF GOODS SOLD	25 - 28	21 - 24	24.6	24.1	2%
- RESEARCH AND DEVELOPMENT EXPENSES	-	-	73.8	93.2	-21%
- SELLING, GENERAL & ADMINISTRATIVE EXPENSES	-	-	30.8	29.7	4%
OPERATING EXPENSES (EX. COGS)	~80	~110	104.6	122.9	-15%
OPERATING RESULT	**45 - 50**	**-10 / -15**	**18.5**	**1.2**	1461%
NET RESULT	**36 - 41**	**-**	**12.1**	**-6.8**	-278%
CASH AND CASH EQUIVALENTS (31 DECEMBER)	**-**	**-**	**108.6**	**150.0**	-28%

SOURCE: BASILEA PHARMACEUTICA, VALUATIONLAB

Total revenue exceeded guidance by more than 21% to CHF 148 mn

Total revenue in 2022, which includes BARDA reimbursements, proceeds from the strategic oncology transactions, and other revenue contributions, next to Cresemba and Zevtera revenues, exceeded guidance by more than 21% and amounted to CHF 147.8 mn. Total revenue was boosted mainly by the strong underlying growth of Cresemba, with significant proceeds from oncology transactions offsetting lower BARDA reimbursements. Total revenue for 2023 is expected to increase by approximately 5% to 7%, boosted by the continued strong growth of Cresemba offsetting lower proceeds from strategic oncology transactions (only approximately CHF 2.5 mn near-term milestones expected in 2023) and the absence of BARDA reimbursements.

Cresemba & Zevtera-related revenue beat guidance by >17% to CHF 122 mn

2022 revenue for both hospital anti-infectives amounted to CHF 122.3 mn, exceeding the company's FY 2022 guidance by more than 17%. In 2023, Basilea guides Cresemba & Zevtera-related revenue to increase by approximately 19% to 21% thanks to underlying solid Cresemba sales uptake, with China and Japan expected to contribute to growth.

Operating costs of CHF 104.6 mn came in lower than guided (around CHF 110 mn), while **COGS** of CHF 24.6 mn were slightly higher than guided (between CHF 21-24 mn) due to solid demand for Cresemba. **R&D expenses** decreased by 21% to CHF 73.8 mn following the conclusion of the costly Zevtera phase III "ERADICATE" trial that reported positive results in bacteremia in June 2022. **S, G&A expenses** remained relatively flat (+4%) at CHF 30.8 mn.

A positive net cash flow of CHF 7.1 mn was provided by operating activities. The debt level was reduced without diluting shareholders. The **balance sheet** was strengthened with the repayment of the 2022 convertible bonds, with the final

outstanding amount of CHF 113.8 mn fully repaid in December 2022, financed through the CHF 75 mn Athyrium loan and cash at hand. **Cash and cash equivalents** (including restricted cash) declined by 28% to CHF 108.6 mn, mainly due to the repayment of the 2022 convertible bonds.

CRESEMBA - Continued sales success; China & Japan to contribute to growth
Cresemba & Zevtera-related revenue was boosted mainly by the substantial commercial success of Cresemba, which triggered several sales milestone payments from its partners in the US (Astellas), China & Asia Pacific (Pfizer), Canada (Avir Pharma), and the Nordics (Unimedic). According to IQVIA, total global in-market sales of Cresemba increased by 19% to USD 363 mn (12 months to September 2022).

Cresemba has now been approved in 73 countries and launched in around 65 countries, including the US, most EU member states, China, and other countries inside and outside Europe. Last year, Cresemba was launched in China, one of the most important markets for novel branded antifungals, representing approximately 21% of global sales for newer antifungals. In December, Asahi Kasai received marketing approval in Japan (~4% of global sales of newer antifungals), with a launch targeted soon. In February 2022, the strong sales performance in Asia Pacific and China exceeded a threshold triggering a USD 1.25 mn sales milestone from partner Pfizer. This is the second sales milestone payment within eight months, underlining the significant commercial opportunity in this region.

Patient recruitment for the Cresemba pediatric program was completed. This is a requirement for gaining an additional two years of pediatric market exclusivity in the EU and 6 months in the US. The pediatric filing in the EU and US is planned for H2 2023 with approval expected roughly a year later.

ZEVTERA - US filing for three indications, including SAB, ABSSSI, and CABP
Following a pre-NDA (New Drug Application) meeting with the FDA in Q4 2022, Basilea will seek approval not only for SAB (*Staphylococcus aureus* bacteremia) based on the positive phase III “ERADICATE” trial and ABSSSI (acute bacterial skin and skin structure infections) based on the positive phase III “TARGET” trial but also for CABP (community-acquired bacterial pneumonia) based on earlier bacterial lung infection trials. Although SAB has the highest unmet medical need, a broader indication would support further use of Zevtera in the clinical practice setting. Upon launch, the company will focus on SAB and broaden the use of Zevtera in other indications over time.

In our view, contracting a US commercialization partner and approving and launching Zevtera in the lucrative US market should significantly boost Zevtera’s revenues. Zevtera enjoys at least 10 years of US market exclusivity from approval

PRECLINICAL – Next decision DXR inhibitor in 2023 – FCCDC program returned
The progress on advancing earlier internal programs continues. The work on the in-licensed DXR inhibitor program against multidrug-resistant Gram-negative bacteria advanced, with the next preclinical decision point expected in 2023. The profiling was completed of a lead compound from the recently in-licensed preclinical program of broad-spectrum antifungals with a new mode of action from the Fox Chase Chemical Diversity Center (FCCDC). The candidate did not meet Basilea’s stringent criteria for progressing into the development stage and was returned to FCCDC.

2023 GUIDANCE – Cresemba growth to continue and net profit to at least triple

As seen in the table above, Basilea guides for another strong performance in 2023. Cresemba & Zevtera-related revenue is expected to increase by 19-21%, with China and Japan expected to add to the substantial commercial success of Cresemba. Operating profit is expected to increase to CHF 45-50 mn and net profit to at least triple to CHF 36-41 mn. Basilea plans to continue reducing its debt level through the partial repayment of the CHF 75 mn Athyrium loan in the amount of approximately CHF 37 mn.

Investment case, strategy & cash

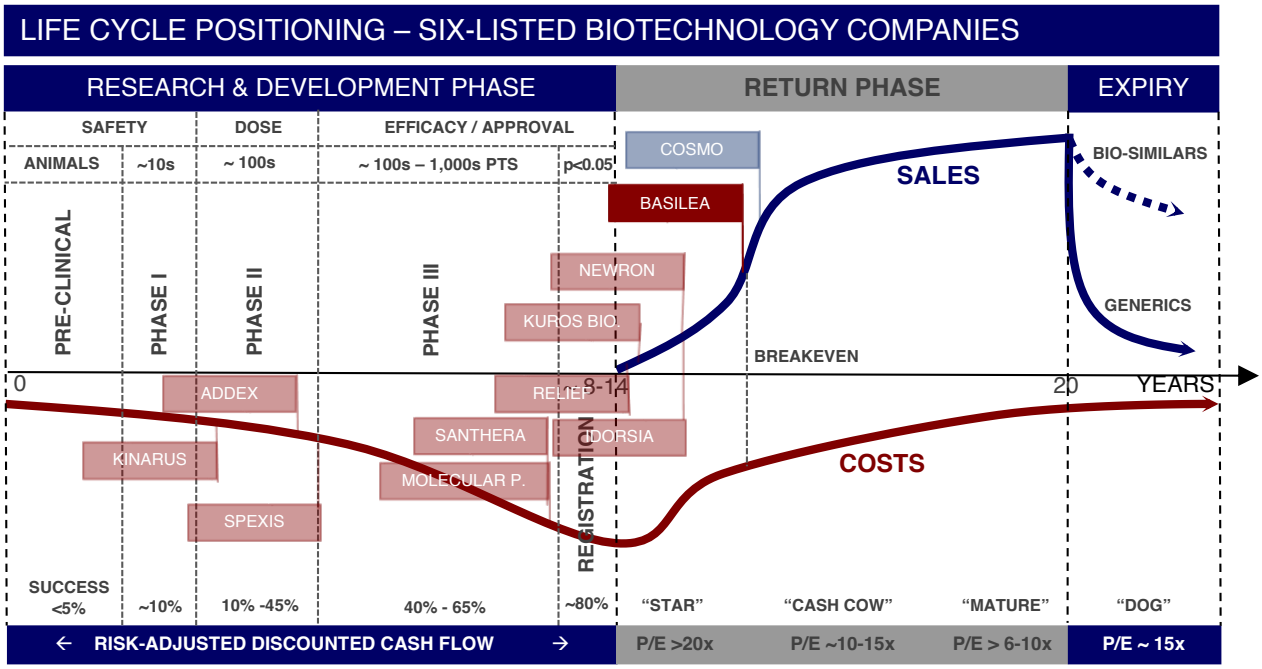
Investment case in a nutshell

Basilea has delivered on its new strategy to become a pure-play anti-infectives research & development company with sustainable profits from 2023 onwards. Its growing revenues are driven mainly by its hospital antifungal Cresemba. Cresemba's strong growth is driven by robust underlying demand and the ongoing global rollout. Zevtera's revenues should receive a substantial boost with the upcoming approval and launch in the lucrative US market in new indications, such as bacteremia and severe skin infections. Basilea's products are marketed through a mix of commercialization and distribution partners globally. Basilea has sufficient cash to fully execute its development plans, in-license external anti-infectives, and deleverage its balance sheet by reducing its debt level. Basilea is one of the few SIX-listed biotech companies with sustained profitability and sufficient cash. Net profit is expected to at least triple in 2023.

Based on our detailed bottom-up forecasts for the company's two key value drivers, Cresemba and Zevtera, with substantial patent life and market exclusivity, we calculate a sum-of-the-parts risk-adjusted NPV for Basilea of CHF 836 mn or CHF 76 per share, providing equity upside of 80% from the current low share price. The contracting of a US commercialization partner, and the launch of Zevtera in the US (mid-2024), should provide substantial upside.

Life Cycle Positioning – Medium Risk

We qualify an investment in Basilea as Medium Risk. The company has a sizeable gross cash position and has reached sustained profitability thanks to increasing product revenues from Cresemba and Zevtera. Proceeds from transactions for its oncology assets and upfront and milestone payments from a US partnering deal for Zevtera could further boost Basilea's cash position (See Important Disclosures for our Risk Qualification).



SOURCE: VALUATIONLAB

Focus on anti-infectives to target rising anti-infective resistance and non-response
Basilea is a Swiss biopharmaceutical company dedicated to discovering and developing hospital prescription drugs to treat severe bacterial and fungal infections, targeting the challenge of rising resistance and non-response to current treatments. Basilea was spun-off from Roche in October 2000 with early-stage pipeline projects consisting of the hospital antibiotic ceftobiprole (branded "Zevtera" and "Mabelio" in certain countries), the hospital antifungal isavuconazole (branded "Cresemba"), and the chronic hand eczema treatment alitretinoin (branded "Toctino"). Basilea exited the dermatology field in 2012 when it transferred the worldwide rights of Toctino to Stiefel, a GlaxoSmithKline (GSK) company, in return for CHF 225 mn. In early 2022, the company decided to exit oncology and largely transacted its oncology assets to accelerate Basilea's path to sustained profitability from 2023 onwards. Basilea has approximately 140 employees following the successful divestment of its Chinese R&D subsidiary in April 2021 and its exit from oncology in 2022. Its integrated research covers broad areas of expertise to combat drug resistance, such as microbiology, biochemistry, pharmacology, analytics, and medicinal chemistry, among others. Basilea was listed on the SIX Swiss Stock Exchange (ticker: BSLN) in March 2004. The company's corporate headquarters are based in the Switzerland Innovation Park Basel Area in Allschwil, Switzerland.

Marketed anti-infectives Cresemba and Zevtera fund the growth of Basilea's pipeline
Basilea has successfully developed and brought its clinical development projects to market. The company's current product offering includes two revenue-generating hospital anti-infectives, the antifungal Cresemba and the antibiotic Zevtera, complemented by a preclinical DXR inhibitor and an in-licensed antifungal program. Revenue from Cresemba and Zevtera is being reinvested, together with external funding, such as from the Biomedical Advanced Research and Development Authority (BARDA) and CARB-X, to develop and expand its anti-infectives pipeline offering.

Anti-infectives product pipeline:

1) **Cresemba (fungal infections - peak sales CHF 650+ mn):** profitable, marketed for severe fungal infections by Astellas in the US, by Pfizer in Europe (excl. the Nordics where Unimedic is responsible) and China & Asia Pacific Region, and various distribution partners globally; more than USD 373 mn in-market sales in the 12 months to December 2022; currently marketed in 63 countries (including the US, major European countries, Australia, Brazil, Saudi Arabia, and Taiwan) and was approved in 73 countries by year-end 2022; license and distribution agreements cover about 115 countries, launches in China (~21% of global sales for newer antifungals) and approval in Japan (by development & commercialization partner Asahi Kasei) occurred in 2022; launch in Japan (~4% of global sales for newer antifungals) in March 2023 triggered a CHF 5 mn milestone payment from Asahi Kasei.

2) **Zevtera (lung infections - peak sales CHF ~50 mn):** profitable, marketed for severe lung infections by various distribution partners such as Advanz Pharma in Europe, Unimedic in the Nordics, Knight Therapeutics in Latin America, Hikma in the MENA region, JSC Lancet in Russia and Eurasian Economic Union countries, and development & commercialization partner CR Gosun in China, Hong Kong, Macao (approved in China in November 2020); currently marketed in 20 countries, license and distribution agreements cover more than 80 countries.

3) **Zevtera (bacteremia & skin infections - peak sales CHF 300+ mn):** successfully completed phase III development for US approval under Special Protocol Assessment (SPA) through two cross-supportive phase III trials, namely "TARGET" for acute bacterial skin & skin structure infections (ABSSSI) and "ERADICATE" for Staphylococcus aureus bacteremia (SAB); BARDA covered ~70% of development costs; US New Drug Application (NDA) for SAB, ABSSSI and CABP (community-acquired bacterial pneumonia) expected to be submitted in Q3 2023, US approval likely in Q2 2024; contract a US commercialization partner in return for substantial milestones and sales royalties expected before US approval; the US represents the most crucial region for branded anti-MRSA hospital antibiotics and should provide a substantial boost to Zevtera revenues.

4) **DXR inhibitor program (Gram-negative bacteria - peak sales TBD):** a novel class of antibiotics targeting drug-resistant Gram-negative bacteria such as carbapenem-resistant Enterobacterales, Acinetobacter baumannii, and multidrug-resistant Pseudomonas aeruginosa; CARB-X research grant of up to USD 2.7 mn received in May 2021.

Few players to address increasing resistance - positive regulatory environment

In the face of multidrug-resistant pathogens becoming a new global health threat, Basilea is one of the few companies worldwide committed to the research and development of new antifungals and antibiotics to combat life-threatening infections. It is estimated that 100,000 Americans and 25,000 Europeans die yearly from hospital-acquired bacterial infections, with many resistant to current antibiotics, and the number is on the rise. The US Centers for Disease Control and Prevention (CDC) estimates that at least 2.8 mn people in the US suffer from antibiotic resistance annually, and at least 35,000 die as a result. An estimated 25 mn patients per year are treated for hospital bacterial infections in key markets, with an estimated 7.5 mn for severe hospital lung infections. A recent study about the global burden of bacterial antimicrobial resistance (AMR) estimated 1.27 mn deaths directly caused by infections with antibiotic resistance in 2019. If this development continues, many more people will suffer from bacterial infections that may still be easily treatable today but not so in the future if new, effective antibiotics are developed against resistant pathogens. Basilea's marketed hospital antibiotic Zevtera targets a USD 2.6 bn global anti-MRSA antibiotic market, where many bacterial infections no longer respond to current antibiotics. The company's DXR inhibitor program has promise in treating Gram-negative bacteria.

Invasive fungal infections have increased worldwide and represent a threat to immunocompromised patients such as cancer patients and patients undergoing solid organ or stem cell transplants. These invasive fungal infections are associated with high mortality rates, ranging from 25-38% (Candida) to 34-58% (Aspergillus) and 40-80% (Mucorales). Basilea's marketed hospital antifungal Cresemba targets a USD 2.8 bn global market.

To encourage activities in these fields, several initiatives have been or are being launched across the globe, such as:

- **Bad Bugs Need Drugs** initiative by the IDSA (Infectious Disease Society of America) in 2011: aiming at ten new antibiotics by 2020
- **Action Plan against antimicrobial resistance** by the European Commission in 2011: 12 actions to be implemented in the EU to tackle antimicrobial resistance (AMR)

- **GAIN** (Generating Antibiotic Incentives Now) Act of 2012 provides QIDP (Qualified Infectious Disease Product) status with priority review and 5 years of additional US market exclusivity for approved antimicrobials
- **DISARM** (Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms) Act (introduced 2014, under legislation): allows a value-based higher reimbursement for hospital antibiotics
- **BEAM Alliance** launched in 2015 is a network of approximately 70 small and medium-sized European companies involved in the development of innovative products to tackle AMR
- **21 Century Cures Act** a US law enacted in 2016 authorizing USD 6.3 bn, mostly for the NIH to advance pharmaceutical R&D in cancer (Beau Biden Cancer Moon Shot), mental health (BRAIN Initiative), tailored medicine (Precision Medicine Initiative), and opioid abuse
- **CARB-X:** Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) founded in 2016, is a global non-profit partnership accelerating antibacterial products to address drug-resistant bacteria, a leading cause of death around the world. The CARB-X portfolio is the world's most scientifically diverse, early development pipeline of new antibiotics, vaccines, rapid diagnostics, and other products. CARB-X is funded by a global consortium of governments and foundations.
- **ADAPT** (Antibiotic Development to Advance Patient Treatment) Act (proposal): more flexible, accelerated approval pathways for antimicrobials for limited patient populations
- **LPAD** (Limited Population for Antibacterial and Antifungal Drugs) pathway**:** established under the 21 Century Cures Act to advance the development and approval of antibacterial drugs to treat serious or life-threatening infections in limited patient populations with unmet needs
- **FDA statements to foster new tools to fight antimicrobial-resistant infections:** changing the model for reimbursement of certain new antimicrobial drugs that meet critical public health needs, principally their ability to target dangerous multi-drug resistant infections. Acute care institutions would pay a fixed annual licensing fee for access to the drug instead of for each prescription.
- **UK government 20-year vision and 5-year action plan:** Drug-resistant "superbugs" are as big a threat as climate change. By 2040, the UK aims to control and contain AMR (bacteria, viruses, parasites, and other infections) by cutting the number of drug-resistant infections by 10% (5,000 infections) by 2025, preventing at least 15,000 patients from contracting infections because of their healthcare each year by 2024, and reduce the use of antibiotics in humans by 15%. A plan has been outlined to pay up to GBP 100 mn per new antibiotic under a first-of-its-kind subscription-based payment model.
- **AMR Action Fund** developed in collaboration with the World Health Organization, European Investment Bank, and the Wellcome Trust in 2020, expects to invest more than USD 1 bn to bridge the funding gap and respond to the AMR threat that aims to bring 2-4 new antibiotics to market this decade
- **PASTEUR Act:** The Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act, originally introduced in 2020 and then reintroduced in 2021, still has not passed Congress with more than 230 organizations representing healthcare providers, public health professionals, and scientists, and the pharmaceutical industry sent a letter to Congress urging support for the Act. The PASTEUR Act would establish a new avenue of federal support for the development

of new antibiotics that are critically needed for patient care and public health. This approach, which would not be linked to the sales or use of those antibiotics but create a subscription-style payment model, aims to address the challenges of recovering investments in drugs that must be used in a limited fashion to preserve their effectiveness.

- **HERA:** Stimulated by the COVID-19 pandemic, the Health Emergency Preparedness and Response Authority was established in Europe to initially focus on COVID-19 and the procurement of vaccines. A part of the agency may focus on implementing and managing financial incentives across Europe to facilitate innovation in the AMR sector. One possible approach is the issue of transferable exclusivity vouchers to companies that successfully develop new antibiotics for treating bacterial infections on the WHO Global Priority Pathogens List. These vouchers provide 6 months of market exclusivity on any product of choice and can be sold freely. Such a voucher could easily be worth a few hundred million dollars if applied to a blockbuster.

Strong partnerships for Cresemba and Zevtera, covering over 100 countries

Basilea has aggressively expanded the global reach of its two anti-infectives, Cresemba and Zevtera, through extensive partnering and distribution agreements, now covering over 100 countries with more than CHF 325 mn of upfront and milestone payments received and more than CHF 1 bn in potential milestones remaining, next to sales royalties and product sales to distribution partners. As a result, Basilea's Cresemba franchise is now highly profitable thanks to the strong US uptake by partner Astellas and in Europe by partner Pfizer. At the same time, Zevtera in severe lung infections has also become a profitable franchise (according to our detailed product forecasts).

Zevtera partnering and approval in the lucrative US market provide substantial upside

The US is the only sizeable market remaining for a partnership with Zevtera. We expect Basilea to contract a US commercialization partner before FDA approval of Zevtera in SAB, ABSSSI, and CABP, expected in Q2 2024 (assuming Priority Review). The US is the most critical region in the USD 2.6 bn (IQVIA Analytics Link, December 2022) global anti-MRSA hospital antibiotics market, representing up to 85-90% of the worldwide market for specific brands, for instance, in the case of Merck & Co's Cubicin (daptomycin) before its patent expired.

US NDA filing of Zevtera in Q3 2023, approval likely in Q2 2024

In 2018, Basilea started two-cross supportive phase III trials in severe skin infections (the "TARGET" trial), and bacteremia or bloodstream infections (the "ERADICATE" trial) under Special Protocol Assessment (SPA) needed to gain US approval. Qualified Infectious Disease Product (QIDP) status, together with new chemical entity (NCE) exclusivity, effectively provides 10 years of market exclusivity in the US from the date of approval. A contract with the US Biomedical Advanced Research and Development Authority (BARDA) covered up to USD 136.4 mn or approximately 70% of the development costs. In August 2019, the "TARGET" trial in ABSSSI reported positive results, followed by positive results of "ERADICATE" in SAB in June 2022. Based on the positive results of both pivotal trials, Basilea plans to submit an NDA for Zevtera in SAB, ABSSSI, and CABP to the FDA in Q3 2023. US approval is expected to occur in Q2 2024, assuming Priority Review (6-month instead of 10-month review) followed by a launch in mid-2024.

Basilea has nearly completed its planned exit from oncology by 2022
Basilea has made significant progress in implementing the new strategy to exit oncology and expects no material expenses related to oncology activities expected beyond 2022. By the end of 2022, the rights of derazantinib were returned to Merck & Co, the PARG inhibitor program was sold to Nodus Oncology, BAL0891 was sold to SillaJen, and the CLK kinase program was sold to Redona Therapeutics (formerly Twentyeight Seven Therapeutics) (see Appendix, page 41). Due to the projects' early (preclinical) development stage, we have conservatively excluded any revenues from BAL0891, the PARG inhibitor program, and the CLK kinase inhibitor program in our forecasts, except for the upfront and near-term milestone payments.

Basilea retains the option to explore partnering opportunities in the future for its remaining oncology asset, lisavanbulin, a novel oral tumor checkpoint controller in phase II development for recurrent glioblastoma (aggressive brain cancer), with a peak sales potential of CHF 150+ mn. The ongoing phase II trials will no longer be expanded.

Basilea has sufficient cash to approach profitability expected from 2023 onwards
With a gross cash position of CHF 108.6 mn (31 December 2022) and product revenues from Cresemba and Zevtera, Basilea should have sufficient cash to fund its crucial development plans, in-license external anti-infectives to strengthen the pipeline and remain profitable from 2023 onwards, in our view. Further upside to the company's cash position is expected from a lucrative licensing deal with a US commercialization partner for Zevtera and strategic transactions for its remaining oncology assets.

Non-dilutive payment of 2022 convertible bond secured through a loan agreement
In September 2022, Basilea closed a CHF 75 mn senior secured loan agreement with Athyrium Capital Management, LP. The loan was used for the non-dilutive repayment of the convertible bonds due on 23 December 2022 with an outstanding nominal amount of CHF 113.8 mn, with the remainder paid with cash at hand. The loan has a two-year term with repayment to start in Q1 2023 every quarter. Interest payments, excluding fees, are estimated at approximately CHF 1.25 mn per quarter of the term. Basilea intends to repay the loan within two years.

Key priorities include Cresemba and Zevtera and executing transactions for broadening R&D anti-infectives pipeline
In the next 12-18 months, Basilea will focus on:

- Increasing Cresemba and Zevtera revenues together with its partners, including increasing contributions from markets outside the US and Europe such as China and Japan
- Submission of pediatric use of Cresemba in H2 2023, potentially extending its market exclusivity by 2 years in the EU and 6 months in the US
- Filing for US approval of Zevtera in the lucrative US market in Q3 2023 and seeking a strong US commercialization partner in return for upfront, regulatory, and substantial sales milestones and royalties on net sales to secure a high share of the value generated over the lifetime of Zevtera in the US market
- Delivering on its solid guidance for FY 2023
- Exploring opportunities to selectively expand the clinical and preclinical anti-infectives portfolio through both in-licensing and internal development
- Advancing its preclinical anti-infective assets

Valuation Overview

Sum-of-parts risk-adjusted NPV (rNPV) points to a fair value of CHF 76 per share
We derive a sum-of-parts rNPV of CHF 76 per share for Basilea, with gross cash of CHF 10 per share (31 December 2022) and overhead expenses of CHF 16 per share (including annual overhead expenses and the repayment of the CHF 75 mn Athyrium loan and convertible bonds in 2027), assuming a WACC of 7% reflecting the low Swiss interest environment.

Basilea's key value drivers:

SUM OF PARTS

PRODUCT	INDICATION	PEAK SALES (CHF MN)	LAUNCH YEAR (EST)	UNADJUSTED NPV/SHARE * (CHF)	SUCCESS PROBABILITY	RISK-ADJUSTED NPV/SHARE * (CHF)	PERCENTAGE OF TOTAL
ANTI-INFECTIVES: CORE							
CRESEMBA	MOLD INFECTIONS (ASPERGILLUS)	666	2015/16	58	100%	**58**	63%
ZEVTERA (EU/ROW)	SEVERE BACTERIAL LUNG INFECTIONS	49	2015	5	100%	**5**	5%
ZEVTERA (GLOBAL)	BACTEREMIA (BLOODSTREAM INFECTIONS)	205	2024	15	80%	**12**	13%
ZEVTERA (GLOBAL)	SEVERE BACTERIAL SKIN INFECTIONS	107	2024	7	80%	**5**	6%
DXR INHIBITOR PROGRAM	GRAM-NEGATIVE BACTERIAL INFECTIONS	TBD	TBD	TBD	0%	TBD	0%
ONCOLOGY: NON-CORE - TO BE EXITED IN 2022							
ONCOLOGY ASSET TRANSACTIONS	VARIOUS CANCERS	TBD	TBD	12	20%	**2**	3%
GROSS CASH (INCL. CONVERTIBLE BONDS) (31 DECEMBER 2022)		109		10		**10**	11%
TOTAL ASSETS				107		**93**	**100%**
OVERHEAD EXPENSES (INCL. REPAYMENT OF CONVERTIBLE BONDS)				-16		**-16**	
NPV/SHARE (CHF)				91		**76**	
SHARE PRICE ON APRIL 26, 2023						42.5	
PERCENTAGE UPSIDE / (DOWNSIDE)						80%	
ESTIMATES AS OF 26 APRIL 2023						SOURCE: VALUATIONLAB ESTIMATES	

Cresemba (invasive mold infections) - NPV of CHF 58/share
We forecast peak sales for Cresemba to amount to CHF 650+ mn, which reflects the excellent sales uptake driven by its competitive profile (e.g., a broad spectrum of activity, easy and convenient (IV and oral) administration, outstanding safety, and tolerability profile), the rise in invasive fungal infections, and a continued global rollout by its commercialization partners. Over 100 countries are covered by partnerships, including Astellas (US – first launched in early 2015), Pfizer (Europe (excluding the Nordics), Russia, Turkey, Israel, China, and Asia Pacific), and Asahi Kasei (Japan), among others. Cresemba was approved in 73 countries by year-end 2022. We calculate an NPV of CHF 58 per share for Cresemba in treating invasive mold infections, including aspergillosis and mucormycosis in adults.

Zevtera (lung infections – EU/ROW) - NPV of CHF 5 per share
We expect global product peak sales of Zevtera in serious (bacterial) lung infections to amount to CHF ~50 mn. Zevtera is a broad-spectrum hospital anti-MRSA cephalosporin antibiotic, including Gram-negative bacteria, for treating both hospital-acquired bacterial pneumonia (HABP), excluding ventilator-associated bacterial pneumonia (VABP), and community-acquired bacterial pneumonia (CABP). Zevtera is approved and marketed by partners in selected major European countries (Advanz Pharma), the Nordics (Unimedic Pharma) and several non-European countries in Latin America (Knight GBT), the MENA region (Hikma), and Canada (Avir Pharma). CR Gosun will develop and commercialize Zevtera in China, Hong Kong, and Macao. Zevtera is not yet approved in the US (see below). We calculate an NPV of CHF 5 per share for Zevtera in treating serious (bacterial) lung infections alone.

Zevtera (new US development plans) – rNPV of CHF 17/share

In the US, Zevtera enjoys QIDP (Qualified Infectious Disease Product) status for its potential use in community-acquired bacterial pneumonia (CABP), acute bacterial skin and skin structure infections (ABSSSI), and Staphylococcus aureus bacteremia (SAB) bloodstream infections. This extends market exclusivity to 10 years from approval in the US, substantially prolonging protection from cheap generics beyond US patent expiry and making it worthwhile developing and seeking approval for these indications in the lucrative US market. Basilea gained Special Protocol Assessment (SPA) for two cross-supportive phase III trial protocols for ABSSSI (the "TARGET" trial) and SAB (the "ERADICATE" trial) required for US approval in April 2017. Approximately 70% of funding was secured through a BARDA agreement. In August 2019, positive pivotal "TARGET" trial results in ABSSSI were announced, followed by positive pivotal "ERADICATE" trial results in SAB in June 2022. The NDA submission for Zevtera in SAB, ABSSSI and CABP is planned for Q3 2023 with approval in Q2 2024. Commercialization is planned through a partnership before US approval in return for considerable upfront, regulatory, and sales milestones and royalties on net sales.

Each indication provides considerable upside:

- **Staphylococcus aureus bacteremia (global) – rNPV of CHF 12/share**
- **Severe skin infections (global) – rNPV of CHF 5/share**

Emerging preclinical pipeline

Basilea's anti-infective pipeline currently includes a single disclosed preclinical project and undisclosed internal programs. Given the early stage (preclinical) of development, we conservatively exclude these pipeline projects from our forecasts.

> **DXR inhibitor program (Gram-negative bacteria - peak sales TBD):** a novel class of antibiotics targeting drug-resistant Gram-negative bacteria such as carbapenem-resistant Enterobacterales, Acinetobacter baumannii, and multidrug-resistant Pseudomonas aeruginosa; CARB-X research grant of USD 2.7 mn received in May 2021.

Oncology asset transactions – rNPV of CHF 2/share

We conservatively excluded any revenues from the recently sold oncology assets BAL0891, the PARG inhibitor program, and the CLK kinase inhibitor program in our forecasts due to the early (preclinical) development stage, except for the upfront and near-term milestone payments. Basilea retains the option to explore partnering opportunities in the future for its remaining oncology asset, lisavanbulin, a novel oral tumor checkpoint controller in phase II development for recurrent glioblastoma (aggressive brain cancer), with a peak sales potential of CHF 150+ mn. We calculate a blended rNPV of CHF 29 mn or CHF 2 per share with a conservative 20% success rate for Basilea's oncology assets.

Sensitivities that can influence our valuation

Patent & market exclusivity: Cresemba's COM (composition of matter) US patent expires in 2025. Protection beyond this period will rely on ODD (orphan drug designation) exclusivity of 7 years in the US and 10 years in the EU. As Cresemba has been granted QIDP (Qualified Infectious Disease Product) designation, 5 years of market exclusivity can be added to the ODD exclusivity providing a total of 12 years of exclusivity from approval in the US until 2027. Cresemba's EU ODD market exclusivity ends in 2025 but could be extended by 2 years to 2027 if the pediatric program is completed (extends US exclusivity by 6 months). In January 2023, Basilea announced that patient enrollment into the pediatric program was completed. Zevtera exclusivity lasts until mid-2024 in the EU, consisting of a COM patent (mid-2019) and 5 years SPC (supplementary protection certificate). There would be a potential for a 1-year extension on regulatory exclusivity on new substantial indications (e.g., bacteremia). In the US, Zevtera received QIDP designation for treating lung, skin, and bloodstream infections resulting in 10 years of exclusivity upon approval, irrespective of patent status.

Commercialization through external partners & distributors: Basilea's revenues will largely depend on external commercialization partners to successfully position and market Cresemba and Zevtera against existing and upcoming treatments. License and distribution agreements for Cresemba and Zevtera currently cover more than 100 countries. The uptake may differ from our forecasts, while the pace of launching and signing on distributors and terms may differ. Commercialization of Cresemba in the US through Astellas is more straightforward, although here, too, uptake and terms may vary.

Pricing and reimbursement: After the formal approvals of Zevtera and Cresemba in Europe, the drugs must be priced and reimbursed by local healthcare providers on a country-by-country basis. In the US, pricing and reimbursement are pretty straightforward. Outside the US, pricing and reimbursement occur on a country-by-country base, leading to different pricing and reimbursement levels and timings.

Antimicrobial stewardship: A shift towards antimicrobial stewardship may influence current antibiotic prescriber behavior. This is a systematic effort to educate and persuade prescribers of antimicrobials to follow evidence-based prescribing to contain antibiotic overuse and, thus, antimicrobial resistance. For instance, some hospitals seek to limit the development of strongly resistant strains by cycling drugs in and out of use on a schedule. Although barely implemented, antimicrobial stewardship could have a significant impact on forecasts, depending on whether Zevtera would be kept in reserve at hospitals.

Availability of generic versions of key competitor treatments: Several of the largest-selling hospital antibiotics and antifungals are losing or have lost patent protection, including Pfizer's antibiotic Zyvox and antifungal Vfend. The availability of cheap generic versions of these drugs may lead to therapeutic substitution affecting newly launched treatments. Treatment resistance due to the broad use of these drugs, and the need for new drugs to treat drug-resistant pathogens, may mitigate the impact. The agreement with Pfizer for Cresemba underlines the potential of new branded anti-infectives, where a high unmet medical need remains for safe, well-tolerated drugs with a broad spectrum of activity.

Catalysts

CATALYST TIMELINES

TIME LINE	PRODUCT	INDICATION	WHAT	COMMENT	IMPACT ON RNPV (PER SHARE)
2023					
9 JAN	CRESEMBA	FUNGAL INFECTIONS	ASTELLAS SALES MILESTONE	STRONG US CRESEMBA SALES IN 2022 TRIGGER A CHF 20 MN SALES MILESTONE PAYMENT FROM ASTELLAS	
11 JAN			PRELIMINARY 2022 REVENUE	UNAUDITED 2022 PRELIMINARY REVENUES ANNOUNCED WITH TOTAL REVENUE EXCEEDING GUIDANCE, UP BY MORE THAN 21% TO CHF ~148 MN BOOSTED BY STRONG CRESEMBA REVENUE, PROCEEDS FROM ONCOLOGY TRANSACTIONS AND OTHER REVENUE; CRESEMBA AND ZEVTERA REVENUE EXCEEDING GUIDANCE, UP BY MORE THAN 17% TO CHF ~122 MN; TARGET REACHED OF CRESEMBA APPROVED IN MORE THAN 70 COUNTRIES BY YEAR-END; US FILING ZEVTERA IN SAB, ABSSSI AND CABP EXPECTED IN MARCH/APRIL 2023; RIGHTS OF NOVEL ANTIFUNGAL FROM FOX CHASE CHEMICAL DIVERSITY CENTER RETURNED	
14 FEB			FY 2022 RESULTS	FY 2022 RESULTS EXCEED GUIDANCE BOOSTED BY CRESEMBA ROYALTY INCOME UP 22.4% TO CHF 65 MN, CRESEMBA AND ZEVTERA MILESTONES OF CHF 23.4 MN, CHF 15 MN FROM ONCOLOGY TRANSACTIONS AND CHF 8.4 MN BARDA REIMBURSEMENTS; R&D COSTS DECREASED BY 21% TO CHF 73.8 MN WHILE S,G&A REMAINED LARGELY FLAT AT CHF 30.8 MN; AN OPERATING PROFIT OF CHF 18.5 MN AND NET PROFIT OF 12.1 MN WAS RECORDED FOR 2022; 2023 GUIDANCE: CRESEMBA & ZEVTERA RELATED REVENUE OF CHF 145-148 MN, ROYALTY INCOME OF AROUND CHF 74 MN, TOTAL REVENUE OF CHF 155-158 MN, COGS OF CHF 25-28 MN, OPERATING EXPENSES OF AROUND CHF 80 MN, OPERATING PROFIT OF CHF 45-50 MN, NET PROFIT OF CHF 36-41 MN	
23 MAR	CRESEMBA	FUNGAL INFECTIONS	LAUNCH IN JAPAN	LAUNCH IN JAPAN BY PARTNER ASAHI KASEI TRIGGERED CHF 5 MN MILESTONE FOR BASILEA; SIGNIFICANT GROWTH POTENTIAL, JAPAN IS ~4% OF THE GLOBAL BRANDED HOSPITAL ANTIFUNGAL MARKET	
18 APR	ZEVTERA	SAB* / ABSSSI ** / CABP ***	NDA FILING FOR US APPROVAL	NDA (NEW DRUG APPLICATION) FILING FOR US APPROVAL OF ZEVTERA IN STAPHYLOCOCCUS AUREUS (SAB) AND ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS (ABSSSI) DELAYED BY 3-6 MONTHS TO Q3 2023 DUE TO ADAPTION OF THE QUALITY SYSTEMS OF A CONTRACT MANUFACTURING ORGANIZATION (CMO) TO ENSURE THE CMO IS READY FOR FDA INSPECTION	
26 APR			AGM	ALL BOARD PROPOSALS ACCEPTED BY SHAREHOLDERS AT THE ANNUAL GENERAL MEETING (AGM); DOMENICO SCALA RE-ELECTED AS CHAIRMAN OF THE BOARD, DR. CAROLE SABLE ELECTED AS NEW BOARD MEMBER	
Q3	ZEVTERA	SAB* / ABSSSI ** / CABP ***	NDA FILING FOR US APPROVAL	NDA (NEW DRUG APPLICATION) FILING FOR US APPROVAL OF ZEVTERA IN STAPHYLOCOCCUS AUREUS (SAB) AND ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS (ABSSSI) BASED ON THE TWO POSITIVE CROSS-SUPPORTIVE PHASE III "ERADICATE" AND "TARGET" TRIALS AND COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA (CABP) BASED ON PREVIOUS LUNG INFECTION TRIAL	
15 AUG			H1 2023 RESULTS	H1 2023 RESULTS RELEASE AND INVESTOR CALL TYPICALLY AT 4 PM CEST	
H2	ZEVTERA	SAB* / ABSSSI ** / CABP ***	US PARTNER	US PARTNER EXPECTED TO BE CONTRACTED AHEAD OF US APPROVAL OF ZEVTERA IN RETURN FOR UPFRONT AND SALES MILESTONE PAYMENTS AND ROYALTIES ON NET SALES	
H2	CRESEMBA	FUNGAL INFECTIONS	PEDIATRIC FILING	EU AND US FILING FOR USE OF CRESEMBA IN CHILDREN 6 YEARS AND ABOVE; PEDIATRIC APPROVAL PROVIDES 2-YEAR MARKET EXCLUSIVITY IN THE EU AND 6 MONTHS IN THE US	
2023 AND BEYOND	NEW ANTI-INFECTIVES	BACTERIAL OR FUNGAL INFECTIONS	IN-LICENSING NEW COMPOUNDS	IN-LICENSING OF ANTIFUNGALS OR ANTIBIOTICS FROM LATE PRECLINICAL UP TO LATE PHASE II DEVELOPMENT TO EXPAND THE PIPELINE OFFERING AND LEVERAGE DEVELOPMENT EXPERTISE	
2023 AND BEYOND	NEW ANTI-INFECTIVES	BACTERIAL OR FUNGAL INFECTIONS	INTERNAL PROGRAMS	BASILEA EXPECTS TO ADVANCE ITS INTERNAL ANTI-INFECTIVE DISCOVERY PROGRAMS TO CLINICAL DEVELOPMENT TO EXPAND ITS PIPELINE OFFERING	

*SAB =STAPHYLOCOCCUS AUREUS BACTEREMIA; **ABSSSI = ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS; *** CABP = COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA
ESTIMATES AS OF 26 APRIL 2023

SOURCE: VALUATIONLAB ESTIMATES

Technology & Pipeline

Uniquely positioned to address the threat of resistance through integrated operations
The company is uniquely positioned to address the growing threat of resistance through its integrated R&D and commercial operations. This integrated structure includes all the necessary expertise and technology in-house to innovate and develop new anti-infective treatments and bring them to the market. By integrating all key functions in-house, the company can develop the right market profile for a new compound and guide the selection of the best drug candidate at a very early stage. This approach ensures the timely initiation of all critical activities necessary for chemical and pharmaceutical development, including manufacturing supplies for preclinical and clinical trials.

All required technologies in-house to advance research projects rapidly
Basilea has all the required technologies and skills to carry out lead optimization to final clinical candidate selection efficiently. Core strengths include biochemistry, microbiology, analytics, medicinal chemistry, and discovery informatics.

Outsourcing & partnering when needed, but oversight & coordination kept in-house
Basilea outsources its clinical development to CROs (Contract Research Organizations) to minimize fixed costs and retain resource flexibility. Oversight and overall coordination of these activities are kept in-house through a highly experienced management team. Joint Steering Committees keep oversight and coordination in the case of collaborations.

Key advantages of Basilea's integrated operations allow:

- Qualified decision-making from early discovery up to commercialization in a timely manner
- Developing the right market profile for a new drug candidate from the start
- Selecting the best drug candidate at an early stage
- Interaction with key opinion leaders and global health authorities to progress development programs and achieve competitive labeling
- Proven track record in partnering with pharma partners, funding partners, and academic institutions
- Interaction between Basilea's physicians and scientific staff and the international medical community to improve the understanding of patient needs
- Interaction with the external scientific community to enhance in-licensing opportunities
- Sharing of know-how between different disciplines, projects, and external partners to help maximize the output of all efforts and investments

As a result, Basilea has built a differentiated portfolio with potential best-in-class or first-in-class compounds to treat severe bacterial hospital infections and invasive hospital fungal infections that do not or no longer respond to current treatment options, all with high mortality rates.

Differentiated R&D portfolio addressing severe bacterial & fungal infections

PRODUCT PIPELINE

PRODUCT	DRUG CLASS	INDICATION	STATUS	LAUNCH DATE (EXPECTED)	PARTNER	PEAK SALES POTENTIAL
ANTI-INFECTIVES: CORE						
CRESEMBA	BROAD-SPECTRUM TRIAZOLE	INVASIVE MOLD INFECTIONS (ASPERGILLOSIS & MUCORMYCOSIS)	MARKETED	2015 (US) 2016 (EU) 2018 - 2020 (ROW) 2022 (JAP)	ASTELLAS (US) PFIZER (EUROPE EX. NORDICS) DISTRIBUTORS (ROW) ASAHI KASEI (JAPAN)	CHF 650+ MN
ZEVTERA	BROAD-SPECTRUM CEPHALOSPORIN	SEVERE (RESISTANT) LUNG INFECTIONS	MARKETED (EXCEPT US)	2014 (EU) 2017/2018 (EX-US)	DISTRIBUTORS (ROW)	CHF ~50 MN
ZEVTERA	BROAD-SPECTRUM CEPHALOSPORIN	BACTEREMIA (BLOODSTREAM INFECTIONS)	PHASE III (POSITIVE)	2024 (US)	US PARTNER TBD	CHF 200+ MN
ZEVTERA	BROAD-SPECTRUM CEPHALOSPORIN	SEVERE (RESISTANT) SKIN INFECTIONS	PHASE III (POSITIVE)	2024 (US)	US PARTNER TBD	CHF 100+ MN
DXR INHIBITOR PROGRAM	DXR INHIBITOR	MULTI-DRUG RESISTANT GRAM-NEGATIVE BACTERIAL INFECTIONS	PRECLINICAL	TBD	TBD	TBD

ESTIMATES AS OF 26 APRIL 2023

SOURCE: VALUATIONLAB ESTIMATES, BASILEA PHARMACEUTICA

Basilea's key products include:

1. **Cresemba (isavuconazole):** is a marketed intravenous (IV) and oral triazole antifungal for treating invasive hospital fungal infections. Cresemba has a competitive and differentiated profile compared to other in-market azole antifungals, including a broad spectrum of activity against molds, including emerging molds (mucorales), with consistent plasma levels and a manageable drug-to-drug interaction profile, can be administered without restrictions in patients with renal impairment, in a convenient once-daily maintenance dose either IV (hospital-setting) or oral (home-setting) with statistically fewer drug-related and treatment-emergent side effects (liver, skin, eye) in invasive aspergillosis patients compared to voriconazole (branded Vfend by Pfizer) as seen in the pivotal phase III "SECURE" trial. The ECIL-6 guideline states that Cresemba is recommended for the first-line treatment of invasive aspergillosis in leukemia and hematopoietic stem cell transplant patients and is as effective as Vfend, however, with a better safety profile.

   Cresemba is marketed in more than 60 countries, including the US, most EU member states, and additional countries inside and outside Europe. Basilea participates in the commercial success of Cresemba through milestone payments and sales royalties from its license partners, including Astellas for the US and Pfizer for most countries in Europe and China/Asia Pacific, and by selling Cresemba at a transfer price to its distribution partners.

   Cresemba enjoys exclusivity through 2027 in the US and a potential pediatric exclusivity extension to 2027 (from 2025) in the EU.

2. **Zevtera (ceftobiprole):** is a marketed 5th-generation broad-spectrum hospital cephalosporin antibiotic, with rapid bactericidal activity against Gram-positive organisms, including MRSA (methicillin-resistant Staphylococcus aureus) and MSSA (methicillin-susceptible Staphylococcus aureus), as well as Gram-negative bacteria, with a low propensity for resistance development with the potential to replace antibiotic combination treatments. Zevtera has an established safety profile consistent with the cephalosporin class, demonstrated in both adult and pediatric patients.

   Zevtera is currently approved for the treatment of bacterial pneumonia (serious lung infections) and is marketed in selected countries in Europe, Latin America, the MENA region, and Canada through a combination of commercialization and distribution partners.

To gain market access in the US, the commercially most important region for branded anti-MRSA hospital antibiotics, Basilea successfully conducted two cross-supportive phase III trials, the "ERADICATE" trial in SAB (Staphylococcus aureus bacteremia), and the "TARGET" trial in ABSSSI (acute bacterial skin and skin structure infections) and is preparing an NDA (new drug application) to be submitted in Q3 2023. Basilea will also seek approval for a third indication of CABP (community-acquired bacterial pneumonia) based on previously conducted phase III trials. FDA approval will likely occur in Q2 2024, assuming Priority Review (6-month instead of 10-month review). US commercialization is planned through a partnership ahead or shortly after US approval in return for considerable upfront, regulatory, and sales milestones and royalties on net sales.

Based on the granted QIDP (Qualified Infectious Disease Product) designation for SAB, ABSSSI, and CABP, Zevtera is eligible to receive ten years of market exclusivity in the US from the date of approval.

In the following section, we will provide in-depth analyses and forecasts for Basilea's key drivers, including:

- **Cresemba in severe hospital fungal infections** (see page 19)
- **Zevtera in serious hospital bacterial infections** (see page 27)

Forecasts & Sensitivity Analysis

Cresemba (invasive mold infections: aspergillosis & mucormycosis)

Product Analysis

Cresemba peak sales of CHF 650+ mn - NPV of CHF 58 per share

We forecast global peak sales for Cresemba to amount to CHF 666 mn for treating invasive mold infections. Pfizer is fully responsible for European commercialization (excluding the Nordics), Russia, Turkey, Israel, China, and Asia Pacific. We assume market exclusivity until 2027, a treatment price per patient of USD 6,580 (US/Japan) and EUR 5,600 (EU), and a market penetration peaking at 7% to 26%. In the US, we assume licensing partner Astellas to pay a tiered accumulated royalty rate rising from 15% to ~22% with additional sales milestones conservatively amounting to CHF 50 mn. In Europe, China, and Asia Pacific, we assume Pfizer to pay sales royalties in the mid-teen range with additional regulatory and sales milestones amounting to CHF 193 mn. Outside the Astellas and Pfizer regions (ROW), we assume distributor transfer prices ranging between 35-55% of the wholesale price per patient (EUR 3,920), and declining COGS of 15-9%. Our NPV amounts to CHF 639 mn, or CHF 58 per share, using a WACC of 7% (see page 25).

Astellas, Pfizer, and partners push Cresemba sales higher

Basilea's Cresemba (isavuconazole) is a novel intravenous and oral broad-spectrum antifungal for treating life-threatening invasive fungal infections, including aspergillosis and mucormycosis, with the potential to become a preferred treatment for systemic fungal infections in the hospital setting. Invasive fungal infections are often a complication in patients with a weak immune system and are severe, with high mortality rates of up to 80% in some cases. With more than 1.5 mn people estimated to die of fungal infections yearly, invasive fungal infections are emerging as a significant global healthcare threat.

Cresemba targets a USD 2.8 bn (MAT Q4 2022, IQVIA Analytics Link) global antifungal market. Thanks to its competitive and differentiated profile, Cresemba has become the market leader in the US in terms of value among best-in-class antifungals and has consistently increased its market share to currently 34% (December 2022) in best-in-class antifungals since its launch in 2015. Global in-market sales of Cresemba increased to more than USD 373 mn in the 12 months to December 2022. Sustainable long-term growth is expected to be supported by new launches, such as in China, where it was recently launched. China accounts for approximately 20% of global sales for newer antifungals. Approval in Japan, another important market of ~4% of global sales for newer antifungals, occurred in December 2022, with the launch in March 2023 triggering a CHF 5 mn milestone payment. Approval is based on the successful abbreviated clinical development program for Japanese approval conducted by partner Asahi Kasei.

Cresemba marketed in more than 60 countries globally by major pharma companies

Cresemba is currently marketed in 63 countries globally, including the US and the major European countries, and approved in 73 countries. Licensing partners include Astellas Pharmaceuticals (US), Pfizer (Europe (excluding the Nordics), China, Asia Pacific), and

Asahi Kasei (Japan). Distributors for Cresemba and Zevtera include Hikma (the Middle East and North Africa – MENA region), Knight Therapeutics (19 Latin American countries), Unimedic Pharma (the Nordics), and Avir Pharma (Canada). See Appendix, page 41.

Astellas agreement: The first major licensing agreement for Cresemba was signed with Astellas in 2010 for commercialization in the US. Basilea is still eligible for up to CHF 240 mn in sales milestone payments and double-digit tiered royalties on US sales starting in the mid-teens and going up to mid-twenties after reaching certain sales levels.

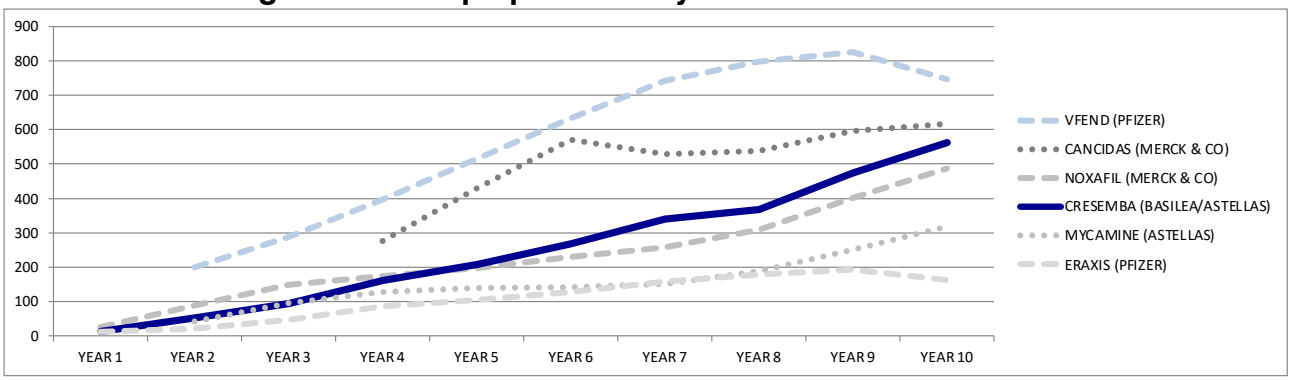
Asahi Kasei agreement: In 2016, Basilea entered into a development and commercialization agreement for Cresemba in Japan with Asahi Kasei. Asahi Kasei has successfully concluded a Japanese phase III registrational trial for Cresemba in invasive fungal infections. Approval in Japan occurred in December 2022, and launched in March 2023, triggering a CHF 5 mn milestone payment. Basilea is still eligible for regulatory and commercial milestone payments of up to CHF 50 mn and double-digit tiered royalties on Japanese sales.

Pfizer agreement: In June 2017, a manufacturing and commercialization agreement was concluded with Pfizer for Cresemba for Europe (excluding the Nordics), Russia (including other CIS countries), Turkey, and Israel, totaling more than 40 countries in Europe. The agreement was extended to China and Asia Pacific under the same terms in December 2017. Basilea is still eligible for additional regulatory and sales milestone payments of up to approximately CHF 580 mn and royalties on sales in the mid-teen range.

Cresemba is on track to reach our peak sales of CHF 650+ mn

After seven years on the market, with staggered launches, first in the US in 2015, followed by the core European countries in 2016, Cresemba has become an important hospital antifungal thanks to its competitive and differentiated profile (see graph below). Cresemba has outperformed other antifungal launches, including Pfizer's Eraxis (anidulafungin), and Astellas' Mycamine (micafungin) sales in their second year on the market. Pfizer's Vfend (voriconazole), which has a broader label (invasive mold AND yeast infections) and was launched globally in its first year, leads the antifungal launch table, followed by Merck & Co's Cancidas (caspofungin), the first echinocandin antifungal on the market.

Overview antifungal sales ramp up from the year of launch



Source: Annual Reports, valuationLAB

Cresemba's sales ramp-up is on track to meet our peak sales forecast of CHF 650+ mn and has already surpassed the initial sales uptake of Merck & Co's Noxafil (posaconazole),

which is used as prevention therapy for patients who are at a high risk of developing invasive mold and yeast infections.

A large medical need with high mortality rates – timely and effective treatment key
Fungal infections are caused by fungi, a group of organisms abundant in nature, such as molds and yeast. Fungal infections are quite common, affecting 20-25% of the general population, are typically superficially restricted to the skin or mucosal surfaces, and do not cause much harm. Invasive or systemic fungal infections are infections where the molds or yeasts have entered the bloodstream or airways and are life-threatening if not treated timely. Mortality rates are high in invasive fungal infections ranging between 23-40% in candida (yeast) infections, 34-58% in aspergillus (mold) infections, and 40-80% in mucorales (emerging mold) infections. Timely intervention with an effective broad-spectrum antifungal is key to improving outcomes.

Invasive fungal infections on the rise with the frequent use of immune suppressants
Invasive fungal infections are typically a complication in immunocompromised patients (patients with a weak immune system), such as patients with HIV, or often caused by treatments that suppress their immune system, such as many cancer drugs to treat solid tumors or leukemia, and organ or stem cell transplants. Invasive fungal infections are on the rise with the increasing use of these immunosuppressant treatments.

Almost 8 mn patients globally per year with an average of 30-40 treatment days
Although invasive fungal infections are far less common than superficial fungal infections, they still affect almost 8 mn patients globally per year (2.3 mn patients in the US and core European markets alone per year), with an estimated 230-300 mn total days of therapy. This means patients are on therapy for an average of 30-40 days, underlining the seriousness of these infections. Half of these invasive fungal infections are related to a stay in the ICU (intensive care unit); the others are treatment-related, 27% leukemia, 11% solid tumors, and the remaining 12% comprise HIV, solid organ, and bone marrow transplant patients.

Three major drug classes - Pfizer's Vfend was the largest-selling antifungal
Cresemba targets a USD 2.8 bn (MAT Q4 2022, IQVIA Analytics Link) global invasive fungal infection market. Three major drug classes target invasive fungal infections, including:

1. **(Tri)azoles:** Pfizer's Vfend (voriconazole – IV & oral) and Merck & Co's Noxafil (posaconazole – IV & oral)
2. **(Echino)candins:** Merck & Co's Cancidas (caspofungin – IV only), Astellas' Mycamine (micafungin – IV only), and Pfizer's Eraxis (anidulafungin – IV only)
3. **Amphotericin B reformulations:** Gilead's / Astellas` AmBisome (IV only)

Cresemba has a competitive profile, in particular, its broad spectrum of activity
The phase III program for Cresemba to evaluate the efficacy and safety in treating invasive fungal infections included three trials (see Appendix, page 42):

1) **"SECURE"** a positive phase III blinded trial for treating invasive aspergillosis
2) **"VITAL"** a positive phase trial open-label trial for treating invasive mucormycosis
3) **"ACTIVE"** a phase III blinded trial to assess the potential for Cresemba as an oral stepdown therapy in adult patients with candidemia and other invasive Candida (yeast) infections where the primary endpoint was missed

Approval of Cresemba in mold infections was based on the two positive pivotal phase III "SECURE" and "VITAL" trials providing a differentiated and competitive profile against existing in-market antifungals. In particular, due to its broad spectrum of activity that covers invasive mold (including mucormycosis) and yeast* (see note below) infections, drives market share across different segments. Furthermore, Cresemba has a more favorable safety profile, can be given to patients with kidney problems, and has a predictable drug exposure, in a convenient once-daily IV (intravenous) or oral formulation.

Amphotericin B compounds such as AmBisome also have a broad spectrum of activity. However, they can only be given intravenously, and their use has been hampered by infusion site reactions and toxicities. Candins such as Cancidas are mostly used in yeast infections (candidemia, esophageal candidiasis). In mold infections (invasive aspergillosis) Cancidas can only be given to patients who are refractory to or intolerant to other therapies such as amphotericin B and azoles. Vfend benefits from having both an IV and oral formulation, next to a broad label for treating mold (invasive aspergillosis but excluding mucormycosis, an emerging mold infection) and yeast (esophageal candidiasis, candidemia) infections. The drug has a less favorable safety profile compared to Cresemba as seen in the "SECURE" trial. Astellas' candin Mycamine is IV-only, with use limited to yeast infections (candidemia, esophageal candidiasis). Generic fluconazole has an IV and oral formulation but is limited to yeast infections with a weaker spectrum of activity.

COMPETITIVE POSITIONING OF CRESEMBA

COMPOUND / CLASS	SPECTRUM		FORMULATION		SAFETY PROFILE
	YEASTS	MOLDS	IV	ORAL	
CRESEMBA	+*	++	YES	YES	+
AMPHO B	+	++	YES	NO	-
CANDINS	++	+/-	YES	NO	+
FLUCONAZOLE	+/-	-	YES	YES	+
VFEND (VORICONAZOLE)	+	+	YES	YES	+/-

SOURCE: VALUATIONLAB, BASILEA PHARMACEUTICA

NOTE: * We believe Cresemba has demonstrated microbiological activity in yeast infections similar to Vfend. Although the phase III "ACTIVE" trial investigating the use of Cresemba in treating invasive yeast infections (Candida) did not meet its primary endpoint of non-inferiority against Cancidas at the end of IV therapy, the overall response rates at two weeks after treatment, as well all-cause mortality were comparable with the Cancidas (IV) / Vfend (oral) treatment group. The overall safety profile of isavuconazole was similar to caspofungin and consistent with safety data seen in the previously reported phase III trials (see Appendix, page 44).

Cresemba's three key points of differentiation:

1) **A broad spectrum of activity:** Cresemba covers invasive aspergillosis and mucormycosis. Vfend does not work in mucormycosis. Mucormycosis occurs in around 10% of invasive mold infections, with a high mortality rate (40-80%). Physicians will be inclined to use Cresemba more empirically because of its broad coverage and the risk of not covering mucormycosis. A delay in using the right treatment from the start significantly increases morbidity and mortality.

2) **Favorable safety profile and can be given to patients with kidney impairment:** Cresemba has demonstrated a more favorable safety profile than Vfend. Cresemba showed fewer side effects with statistically significant differences in several organs such as skin, liver, and eyes. Cresemba is water-soluble, while Vfend is soluble in sulfobutyl ether beta-cyclodextrin sodium and can therefore be given intravenously to patients with renal impairment (32-40% of patients).

3) **Predictable drug exposure:** Cresemba has a consistent pharmacokinetic and pharmacodynamic profile. The linear pharmacokinetics leads to reliable and sufficient levels of active drug in the blood needed to kill fungi (with good data backing this) with fewer peaks and troughs as with Vfend. This could also be one of the reasons why Vfend leads to more side effects.

Cresemba has a manageable drug-drug interaction profile and is a convenient once-a-day IV/oral treatment where no titration is needed when a patient stops IV treatment, typically in a hospital setting, and is switched to oral capsules that can be taken at home.

Important ECIL guidelines recommend Cresemba as a first-line treatment

The important European Conference on Infections in Leukemia (ECIL-6) guideline recommends Cresemba for the first-line treatment (grade AI) of invasive aspergillosis in leukemia and hematopoietic stem cell transplant patients. The guideline states Cresemba is “as effective as voriconazole and better tolerated.” Pfizer’s voriconazole, branded Vfend, is the only other grade AI first-line treatment for these patients. However, “monitoring of serum levels is indicated”, which is not the case with Cresemba. This recommendation, in one of the most relevant treatment guidelines in Europe, underscores the important clinical role of Cresemba in the treatment of patients with these life-threatening infections and should enhance further market penetration.

Detailed Cresemba forecasts based on five regions

In our detailed Cresemba forecasts, we have accounted for Basilea's commercialization plans in five distinctive regions, namely:

1. **European markets** (commercialized by Pfizer)
2. **China** (commercialized by Pfizer)
3. **ROW** (distributors)
4. **US** (commercialized by Astellas)
5. **Japan** (commercialized by Asahi Kasei)

Basilea books product sales in the ROW, where it sells Cresemba to its distributors at a transfer price. In the US, the company receives tiered double-digit royalty on sales from Astellas and is still eligible for up to CHF 240 mn in sales milestones. In Europe (excluding the Nordics), Russia, Turkey, Israel, China, and Asia-Pacific, Basilea will receive royalties in the mid-teen range and is eligible for additional regulatory and commercialization milestones up to USD ~600 mn from Pfizer. In Japan, Basilea will receive double-digit tiered royalties on sales from Asahi Kasei and is eligible for up to CHF 50 mn in regulatory and sales milestones.

Europe: We believe peak sales in Europe could amount to around CHF 220 mn, assuming a treatment price of EUR 5,600 per patient (1-week IV treatment followed by 5 weeks oral treatment), a penetration rate peaking at around 26%, and 10-year orphan drug and 2-year pediatric market exclusivity until 2027.

China: We have included forecasts for China and Asia Pacific to reflect the extension of the Pfizer agreement in December 2017 to this region. We forecast peak sales conservatively to amount to more than CHF 168 mn.

ROW: Peak sales in the ROW are expected to amount to around CHF 59 mn. We assume Basilea sells Cresemba to its distributors at a discounted transfer price. The distributor profits from the difference between wholesale and discounted transfer prices. Basilea benefits from selling Cresemba through an established distribution channel with no other costs than COGS and taxes. We assume the distributor transfer price to start at 35% of the wholesale price (EUR 3,920 per patient), rising to 55% as sales mature.

US: In the US, we forecast peak sales for Cresemba to increase to CHF 250 mn with 12 years of market exclusivity (7 years orphan drug + 5 years QIDP exclusivity) until 2027. We assume a treatment price of USD 6,580 per patient and penetration rates peaking at around 16%. We assume royalty rates on sales start at ~15% and gradually peak at ~22% (this is the average royalty rate over the tiered values). We have conservatively accounted for a total of CHF 50 mn in additional sales milestone payments.

Japan: We expect peak sales in Japan to amount to around CHF 93 mn with first sales starting in early 2023 and similar pricing as in the US. We conservatively account for a total of CHF 25 mn in additional regulatory and sales milestone payments.

Forecasts & Sensitivity Analysis

CRESEMBA (ISAVUCONAZOLE) - FINANCIAL FORECASTS FOR INVASIVE MOLD INFECTIONS

INDICATION	INVASIVE MOLD INFECTIONS (ASPERGILLOSIS AND MUCORMYCOSIS)
DOSAGE	WE ASSUME 6 WEEKS TREATMENT: ONE WEEK 1X DAILY I.V. (200 MG) DOSE FOLLOWED BY 5 WEEKS 1X DAILY ORAL (200 MG) DOSE
PRICE	US/JAP: USD 6,580/PATIENT = 7X USD 240/DAY (IV) + 35X USD 140/DAY (ORAL); EU: EUR 5,600/PATIENT = 7X EUR 350/DAY (IV) + 35X EUR 90/DAY (ORAL); ROW: EUR 3,920/PATIENT
STANDARD OF CARE	NEW AZOLES: E.G. PFIZER'S VFEND (VORICONAZOLE) - EMPERICAL USE WHEN UNKNOWN INFECTION; AMBISOME FOR SUSPECTED MUCORMYCOSIS
UNIQUE SELLING POINT	POTENT BROAD SPECTRUM ONCE DAILY ORAL/IV ANTIFUNGAL WITH RELIABLE DRUG EXPOSURE, LOW TOXICITIES AND BETTER SAFETY IN CERTAIN ORGAN CLASSES

7Ps ANALYSIS

PATENT	US: 2027 = 12 YEARS EXCLUSIVITY (7 YEARS ORPHAN DRUG + 5 YEARS QIDP); EU: 2027 = 12 YEARS EXCLUSIVITY (10 YEARS ORPHAN + 2 YEARS PEDIATRIC)
PHASE	US: APPROVED MARCH 2015; EU: APPROVED OCT. 2015; BASED ON "SECURE" TRIAL IN INVASIVE ASPERGILLUS / "VITAL" TRIAL IN EMERGING MOLDS & RENAL IMPAIRMENT
PATHWAY	QIDP (QUALIFIED INFECTIOUS DISEASE PRODUCT) DESIGNATION IN US; ORPHAN DRUG DESIGNATION IN EU AND US
PATIENT	ONCE DAILY TREATMENT WITH OPTION TO SWITCH IV TO ORAL EASILY; NO NEED FOR TITRATION IN PATIENTS WITH KIDNEY IMPAIRMENT (IV FORMULATION)
PHYSICIAN	NEW TREATMENT WITH BROAD SPECTRUM OF ACTIVITY INCLUDING MUCORMYCOSIS, CAN BE GIVEN TO PATIENTS WITH KIDNEY IMPAIRMENT, NO NEED FOR TITRATION
PAYER	SIGNIFICANT REDUCTION IN HOPITALIZATION AND ALTERNATIVE TREATMENT COSTS
PARTNER	ASTELLAS (US): UP TO CHF 240 MN MILESTONES, D.D. TIERED ROYALTIES; PFIZER (EUROPE, CHINA, ASIA-PACIFIC): UP TO USD 600 MN MILESTONES, MID-TEEN ROYALTIES

REVENUE MODEL

EUROPE (PFIZER)	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**	**2029E**	**2030E**	**2031E**	**2032E**
NUMBER OF PATIENTS	358,685	364,066	369,527	375,070	380,696	386,406	392,202	398,085	404,057	410,117	416,269
GROWTH (%)	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
PATIENTS IN CORE EU MARKETS	143,474	145,626	147,811	150,028	152,278	154,562	156,881	159,234	161,623	164,047	166,508
PENETRATION (%)	16%	19%	21%	24%	26%	23%	9%	4%	1%	1%	0%
NUMBER OF PATIENTS TREATED	23,315	27,305	31,410	35,257	39,288	35,889	14,571	5,916	2,402	975	396
COST OF THERAPY PER PATIENT (CHF)	5,591	5,557	5,549	5,549	5,549	5,549	5,549	5,549	5,549	5,549	5,549
EUROPE SALES (PFIZER) (CHF MN)	**130**	**152**	**174**	**196**	**218**	**199**	**81**	**33**	**13**	**5**	**2**
CHINA, ASIA PACIFIC SALES (PFIZER) (CHF MN)	**5**	**20**	**42**	**64**	**86**	**108**	**123**	**138**	**153**	**168**	**183**
TOTAL SALES EUROPE, CHINA, ASIA PACIFIC (PFIZER) (CHF MN)	**135**	**172**	**216**	**260**	**304**	**307**	**204**	**171**	**166**	**173**	**185**
ROYALTIES (~16%) (CHF MN)	22	28	35	43	50	50	33	28	27	28	30
MILESTONES (INCL. PFIZER SUPPLY AGREEEMENT (CHF MN)	18	10	0	13	0	15	0	13	0	20	21
COGS (%)	15%	14%	0%	0%	0%	0%	0%	0%	0%	0%	0%
COGS (CHF MN)	-19	-21	0	0	0	0	0	0	0	0	0
OPERATING EXPENSES (CHF MN)	-19	-21	0	0	0	0	0	0	0	0	0
PROFIT BEFORE TAX (CHF MN)	**21**	**17**	**35**	**56**	**50**	**66**	**33**	**41**	**27**	**48**	**51**
TAXES (CHF MN)	0	0	0	0	-10	-13	-7	-8	-5	-10	-10
PROFIT (CHF MN)	**21**	**17**	**35**	**56**	**40**	**52**	**27**	**32**	**22**	**38**	**41**

REST OF WORLD (DISTRIBUTORS)	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**	**2029E**	**2030E**	**2031E**	**2032E**
PATIENTS IN DISTRIBUTOR REGIONS	215,211	218,439	221,716	225,042	228,417	231,844	235,321	238,851	242,434	246,070	249,761
PENETRATION (%)	3.0%	3.7%	4.7%	5.7%	6.7%	6.1%	2.4%	1.0%	0.4%	0.2%	0.1%
NUMBER OF PATIENTS TREATED	6,533	8,160	10,500	12,908	15,386	14,055	5,706	2,317	941	382	155
COST OF THERAPY PER PATIENT (CHF)	3,913	3,890	3,884	3,884	3,884	3,884	3,884	3,884	3,884	3,884	3,884
SALES DISTRIBUTOR REGIONS (CHF MN)	26	32	41	50	60	55	22	9	4	1	1
TRANSFER PRICE (%)	40%	45%	45%	50%	50%	55%	55%	55%	55%	55%	55%
BASILEA SALES DISTRIBUTOR REGIONS (CHF MN)	**10**	**14**	**18**	**25**	**30**	**30**	**12**	**5**	**2**	**1**	**0**
COGS (CHF MN)	-3	-4	-5	-6	-7	-7	-3	-1	0	0	0
PROFIT BEFORE TAX (CHF MN)	**7**	**10**	**13**	**19**	**23**	**23**	**10**	**4**	**2**	**1**	**0**
TAXES (CHF MN)	0	0	0	0	-5	-5	-2	-1	0	0	0
PROFIT (CHF MN)	**7**	**10**	**13**	**19**	**18**	**19**	**8**	**3**	**1**	**1**	**0**

UNITED STATES (ASTELLAS)	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**	**2029E**	**2030E**	**2031E**	**2032E**
NUMBER OF PATIENTS	239,124	242,710	246,351	250,046	253,797	257,604	261,468	265,390	269,371	273,412	277,513
PENETRATION (%)	13%	14%	15%	16%	16%	13%	3%	1%	0%	0%	0%
NUMBER OF PATIENTS TREATED	30,847	33,494	36,214	38,757	40,608	32,973	6,694	1,359	276	56	11
COST OF THERAPY PER PATIENT (CHF)	6,162	5,932	5,876	5,876	5,876	5,876	5,876	5,876	5,876	5,876	5,876
SALES (CHF MN)	**190**	**199**	**213**	**228**	**239**	**194**	**39**	**8**	**2**	**0**	**0**
AVERAGE ROYALTY (%)	23%	23%	23%	23%	23%	23%	23%	23%	23%	23%	23%
ROYALTIES (CHF MN)	43	45	48	51	54	44	9	2	0	0	0
UPFRONT & MILESTONE PAYMENTS (CHF MN)	20	14	0	27	0	36	0	0	0	0	0
PROFIT BEFORE TAX (CHF MN)	**63**	**58**	**48**	**78**	**54**	**79**	**9**	**2**	**0**	**0**	**0**
TAXES (CHF MN)	0	0	0	0	-11	-16	-2	0	0	0	0
PROFIT (CHF MN)	**63**	**58**	**48**	**78**	**43**	**63**	**7**	**1**	**0**	**0**	**0**

JAPAN (ASAHI KASEI)	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**	**2029E**	**2030E**	**2031E**	**2032E**
NUMBER OF PATIENTS	97,568	99,519	101,509	103,540	105,610	107,723	109,877	112,075	114,316	116,602	118,935
PENETRATION	0%	5%	7%	9%	10%	11%	12%	14%	11%	3%	1%
NUMBER OF PATIENTS TREATED	0	5,374	7,512	9,422	10,772	12,173	13,625	15,130	12,346	3,778	1,156
COST OF THERAPY PER PATIENT (CHF)	6,162	5,932	5,876	5,876	5,876	5,876	5,876	5,876	5,876	5,876	5,876
SALES (CHF MN)	**0**	**32**	**44**	**55**	**63**	**72**	**80**	**89**	**73**	**22**	**7**
ROYALTIES (~12%) (CHF MN)	0	4	5	7	8	9	10	11	9	3	1
UPFRONT & MILESTONE PAYMENTS (CHF MN)	2	5	4	0	4	0	0	6	5	2	0
PROFIT BEFORE TAX (CHF MN)	**2**	**9**	**9**	**7**	**12**	**9**	**10**	**17**	**14**	**4**	**1**
TAXES (CHF MN)	0	0	0	0	-2	-2	-2	-3	-3	-1	0
PROFIT (CHF MN)	**2**	**9**	**9**	**7**	**9**	**7**	**8**	**14**	**11**	**3**	**1**

	2022E	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**	**2029E**	**2030E**	**2031E**	**2032E**
GLOBAL SALES (CHF MN)	**351**	**434**	**514**	**593**	**666**	**627**	**345**	**277**	**244**	**197**	**193**
CHANGE (%)	15%	24%	18%	15%	12%	-6%	-45%	-20%	-12%	-19%	-2%
GLOBAL PROFIT (CHF MN)	**93**	**94**	**106**	**160**	**110**	**142**	**49**	**50**	**34**	**42**	**42**
CHANGE (%)	-8%	2%	12%	50%	-31%	28%	-65%	3%	-32%	23%	-1%
WACC (%)	7%										
NPV TOTAL PROFIT (CHF MN)	**639**										
NUMBER OF SHARES (MN)	11.0										
NPV PER SHARE (CHF)	**58**										

SENSITIVITY ANALYSIS

		WACC (%)						
	CHF/SHARE	5.5	6.0	6.5	7.0	7.5	8.0	8.5
	800	76	74	78	72	71	69	68
	750	71	70	69	67	66	65	64
	700	66	65	64	63	62	61	60
PEAK SALES (CHF MN)	650	62	60	59	**58**	57	56	55
	600	57	56	55	54	53	52	51
	550	52	51	50	49	49	48	47
	500	47	46	46	45	44	43	43

ESTIMATES AS OF 26 APRIL 2023

SOURCE: VALUATIONLAB ESTIMATES

Unique Selling Point

Cresemba has a broad spectrum of activity covering invasive mold (aspergillus & Mucorales), with a favorable safety profile and predictable drug exposure that can be given to patients with impaired kidneys. Cresemba can be given intravenously (IV) in a healthcare setting, and once the patient has recovered sufficiently, it can be taken at home orally.

7P's Analysis

Patent: Cresemba enjoys 12 years of market exclusivity in the US, consisting of 7 years of orphan drug exclusivity and 5 years of QIDP exclusivity. As the drug was approved in March 2015, US exclusivity lasts until March 2027. In the EU, Cresemba will enjoy 10 years of orphan protection until October 2025, plus 2 years of additional protection when the Pediatric Investigation Plan (PIP) is completed, following its approval in October 2015.

Phase: Cresemba has completed its phase III development program consisting of three trials, “SECURE” and “VITAL” for treating invasive mold infections (Aspergillus and Mucorales), and “ACTIVE” for treating invasive yeast (Candida) infections. Cresemba has been approved for treating invasive mold infections in most major countries, while approval in invasive yeast infections was not pursued, with “ACTIVE” not meeting its primary endpoint.

Pathway: In March 2015, Cresemba was approved in the US for treating invasive aspergillosis and invasive mucormycosis in adults. US commercialization partner Astellas launched in April 2015. In October 2015, Cresemba was approved in the EU for treating invasive mold infections. The European launch started in Q1 2016.

Patient: Patients will benefit from an effective treatment with a good tolerability and safety profile. Moreover, Cresemba could potentially reduce ICU and hospital stays. The oral formulation allows treatment at home as soon as patients have recovered sufficiently.

Physician: Cresemba can be used empirically thanks to its broad spectrum of activity covering aspergillosis and mucormycosis, combined with good safety and tolerability profile, including patients with kidney problems (32-40% of patients). Moreover, Cresemba has fewer drug interactions and can be given together with many other commonly used drugs in this fragile population.

Payer: Cresemba’s favorable profile (e.g., a broad spectrum of activity, safety and tolerability, and predictable drug exposure) improves outcomes and avoids lengthy hospital stays and follow-on treatment. The oral formulation allows patients to be treated at home.

Partner: Basilea is eligible for up to CHF 240 mn sales milestones and significant tiered double-digit royalties on US sales from partner Astellas. We assume the average royalty rate over the tiered values to start at 15% and gradually peak at ~22%. In Europe, China, and Asia Pacific, Pfizer is responsible for commercialization. Basilea is still eligible for up to USD ~600 mn regulatory and sales milestone payments and mid-teen royalties on sales from Pfizer. In Japan, we expect ~12% royalties on sales from Asahi Kasei and CHF 25 mn milestones. Outside these regions, there are distribution agreements for Latin America, the Nordics, Canada, the Middle East, and North Africa. We assume distributor transfer prices to start at 35% of the wholesale price and increase to 55% as Cresemba sales mature.

Zevtera (serious lung, skin & bloodstream infections)

Product Analysis

Zevtera all indications - rNPV of CHF 22 per share

1) Lung infections (EU/ROW): NPV of CHF 5/share; we forecast global peak product sales (excluding the US) of CHF 49 mn. Zevtera was launched in early 2015 in the EU, with market exclusivity until at least 2024, a 10-day treatment price per patient of CHF 1,800 (European markets) and CHF 900 (ROW, excl. US), and a market penetration peaking at around 1-2%. In Europe and ROW (excl. US and China), we assume a distributor transfer price between 35-55% of the wholesale price and COGS between 25-15%. First sales in China, Hong Kong, and Macao by CR Gosun are expected in 2022, where we assume 12% royalties on sales and CHF 26 mn in development and sales milestones. Our NPV amounts to CHF 53 mn or CHF 5 per share, assuming a WACC of 7% (see page 33).

2) Bacteremia (global): rNPV of CHF 12/share: we forecast peak sales of CHF 205 mn with the US launch in mid-2024 and 10-year market exclusivity from approval in the US. We conservatively assume a 21-day treatment price of USD 6,720 per patient, with market penetration peaking at ~6%. We assume Basilea will seek a US commercialization partner ahead or shortly after US approval, expected in 2023, assuming USD 30 mn in upfront sales milestones and 20% royalties on sales. Our rNPV amounts to CHF 128 mn or CHF 12 per share with an 80% (filing) success rate (see page 34).

3) Severe skin infections (global): rNPV of CHF 5/share; we forecast peak sales of CHF 107 mn with first launches in mid-2024, the same market exclusivity as for bacteremia, a 7-day treatment price of USD 2,240, and market penetration peaking at ~4%. We assume the same US partner as Zevtera in SAB with USD 18 mn in upfront and sales milestones and 20% royalties on sales. Our rNPV amounts to CHF 58 mn or CHF 5 per share with the same 80% (filing) success rate as for SAB (see page 35).

The upcoming US launch should lead to a jump in Zevtera sales

Basilea's hospital antibiotic Zevtera (ceftobiprole) provides physicians with a first-line simplified empiric intravenous (IV) treatment option in patients with serious Gram-positive and Gram-negative bacterial infections, including methicillin-susceptible and methicillin-resistant Staphylococcus aureus (MSSA, MRSA) and Pseudomonas spp. 2 infections. Zevtera is well suited to replace a combination of antibiotics often required to treat patients with these serious hospital bacterial infections with a single treatment option thanks to its rapid and broad-spectrum bactericidal activity, low propensity for resistance development, and a safety and tolerability profile, consistent with the cephalosporin class demonstrated in both adult and pediatric patients. The drug has excellent activity against resistant bacteria such as MRSA, which is prevalent in many countries.

Zevtera targets the USD 2.6 bn (IQVIA Analytics, December 2022) global hospital anti-MRSA antibiotic market, with the US being the most important region. The drug is currently approved and marketed as Zevtera and Mabelio in a number of countries in Europe and beyond for the treatment of adult patients with hospital-acquired bacterial pneumonia (HABP), excluding ventilator-associated bacterial pneumonia (VABP) and for the treatment of community-acquired bacterial pneumonia (CABP). Approval was based on two positive phase III trials, including CABP and HABP patients (see Appendix, page 45). Zevtera uptake has been slow as (low) pricing, (regional) reimbursement and hospital formulary listing and inclusion in microbial stewardship programs are typically lengthy, while prescribers tend to

constrain the use of novel antibiotics to avoid the buildup of resistance. We have accounted for a gradual, linear sales uptake for Zevtera in serious lung infections, with peak sales typically reached at the end of exclusivity.

Zevtera has not yet been approved in the lucrative US market. We believe the US development of Zevtera provides a substantial return on investment for Basilea at a relatively low risk. The US can represent up to 85-90% of global sales for a branded hospital anti-MRSA antibiotic. Zevtera was granted Qualified Infectious Disease Product (QIDP) status in the US for the potential use in community-acquired bacterial pneumonia (CABP), acute bacterial skin and skin structure infections (ABSSSI), and Staphylococcus aureus bacteria (SAB) bloodstream infections. If approved in any one of these three indications, Zevtera would be eligible for at least 10 years of market exclusivity, consisting of 5 years of NCE New Chemical Entity (NCE) and another 5 years of QIDP exclusivity. This provides sufficient time to make an attractive return on investment and provides a substantial upside to our Zevtera forecasts.

Basilea intends to enhance and maximize Zevtera's growth potential by:

1) **GLOBAL REACH:** Expanding the global reach and rollout through further partnerships and distribution deals.
2) **US MARKET:** Approval and launch in the lucrative US market after successfully concluding the US phase III development program (~70% paid by BARDA) under SPA that included two cross-supportive phase III trials; "TARGET" for skin infections and "ERADICATE" for bacteremia. The NDA filing for three indications (SAB, ABSSSI, and CABP) is scheduled for Q3 2023, with FDA approval likely in Q2 2024, assuming Priority Review

GLOBAL REACH – Zevtera is covered in over 80 countries by a network of partners
Basilea has entered into license and distribution agreements for Zevtera in Europe, Eurasian countries, Latin America, China, Canada, Israel, and the Middle East and North Africa (MENA region). Zevtera is now covered in over 80 countries worldwide through license and distribution agreements. Licensing partners include Advanz Pharma (Europe excluding the Nordics) and Israel, CR Gosun (China, Hong Kong & Macao), Hikma Pharmaceuticals (including Cresemba for MENA region), Knight Therapeutics (Latin America), Unimedic (including Cresemba for the Nordic countries), Avir Pharma (including Cresemba in Canada), and JSC Lancet (Eurasian Economic Union). A partner for the lucrative US market is expected to occur before US approval. See Appendix, page 41.

Advanz Pharma's distribution agreement covers most of Europe
Advanz has the distribution agreement to commercialize Zevtera in more than 30 countries in Europe (excluding Nordic countries) and Israel. Basilea received an upfront payment of CHF 5 mn and is eligible for additional undisclosed payments upon achieving pre-specified regulatory and commercial milestones. Basilea supplies Advanz with the product at a transfer price (we assume transfer prices start at 35% and eventually rise to 55%).

CR Gosun development and license agreement for China, Hong Kong & Macao
Shenzhen China Resources Gosun Pharmaceutical Company, Ltd (CR Gosun) is responsible for the development and commercialization of Zevtera in China, Hong Kong, and Macao. Basilea is still eligible to receive up to approximately CHF 142 mn

additional payments upon achievement of pre-specified regulatory and commercial milestones and tiered double-digit royalties on product sales (we assume ~12% sales royalties).

US MARKET – NDA filing in Q3 2023, US partner before US approval in Q2 2024

The commercial success of Zevtera depends mainly on its approval in the US. Roughly half of the USD 2.6 bn global anti-MRSA hospital antibiotic sales are generated in the US, typically responsible for 85-90% of branded global hospital antibiotics sales. Basilea gained Special Protocol Assessment (SPA) for the cross-supportive phase III trial protocols for ABSSSI and Staphylococcus aureus bacteremia (SAB –bloodstream bacterial infections). Filing under SPA enables the FDA to provide input into the phase III study design and provide more visibility on the review process because the scientific and regulatory requirements have already been agreed upon. This largely eliminates the regulatory risk, with the commercial risk now the largest risk remaining.

The US phase III program was largely paid for by the Biomedical Advanced Research and Development Authority (BARDA), a division within the US Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response. The BARDA contract covered ~70% of the Zevtera phase III development program. This underlines the relative importance and value of Zevtera in treating life-threatening, often resistant, and difficult-to-treat bacterial infections, a rapidly emerging healthcare threat with limited treatment options, not only in the US but also globally. In particular, the attractive efficacy and safety profile of Zevtera and limited treatment options for bacteremia triggered this agreement, in our view.

The US phase III development program for Zevtera consisted of two cross-supportive phase III trials that reported positive results (see Appendix, page 46):

1) **"TARGET" trial:** a positive phase III double-blind, randomized trial for treating ABSSSI (acute bacterial skin and skin structure infections)
2) **"ERADICATE" trial:** a positive phase III double-blind randomized trial for treating SAB (Staphylococcus aureus bacteremia) or serious bloodstream infections

In accordance with the agreed SPA, Basilea will seek FDA approval for Zevtera for treating patients with SAB and ABSSSI based on the two positive cross-supportive phase III "TARGET" and "ERADICATE" trials in Q3 2023. Additionally, Basilea will file for a third indication for Zevtera to treat patients with community-acquired bacterial pneumonia (CABP) based on the previous positive phase III lung infection trials (see Appendix, page 45). US approval is expected to follow roughly eight months after the submission of an NDA. Basilea plans to seek a US commercialization partner before US FDA approval, expected in Q2 2024, assuming Priority Review.

Treatment-resistance bacteria are a rising challenge in hospitals at a hefty cost

Hospital-acquired bacterial pneumonia (HABP) is associated with significant mortality and has been reported to account for more than 25% of all infections in intensive care units (ICUs). HABP dramatically increases both the hospital length of stay and the cost of care and is associated with an overall mortality of 27–51%, with the elderly having a poorer prognosis. Community-acquired bacterial pneumonia (CABP) is also a significant cause of hospitalization in developed countries, accounting for a considerable number of hospital admissions, especially in the elderly.

Pathogens resistant to hospital antibiotics, particularly MRSA (methicillin-resistant S. aureus) and multidrug-resistant (MDR) S. pneumoniae, are associated with poor outcomes and higher treatment costs, with lengthier stays in hospital and more intensive care required. MRSA accounts for up to 20-40% of all HABP. People with MRSA are 64% more likely to die than people with a non-resistant form of bacterial infection.

Despite a decrease in the incidence of MRSA infections in recent years, the proportion of S. aureus isolates reported as MRSA in 2012 was more than 25% in seven of 30 European countries. MRSA was isolated in 16% of patients with hospital pneumonia (21.4% in HABP and 14.6% in VABP). MRSA is a global problem, with resistant isolates ranging from ~14% in the UK to ~35% in Italy, ~45% in the US, and a staggering ~60% in Japan. The need for new antibiotics that treat these resistant strains is high.

MRSA bacteremia and endocarditis are thought to be the most difficult-to-treat hospital infections. In the US, nearly 120,000 S. aureus bloodstream infections occur yearly, with substantial morbidity and approximately 20% 30-day mortality. There are limited antibiotic treatment options, with only two approved treatments for SAB that cover both MSSA and MRSA. Merck & Co's Cubicin (daptomycin) is the only antibiotic with well-established efficacy in treating bacteremia and endocarditis involving MRSA in well-controlled studies. Daptomycin resistance is still uncommon but has been increasingly reported.

Moreover, daptomycin has no activity in the lung, which can be a limitation if there is concern about a concomitant lung infection. A second treatment option for bacteremia is the hospital antibiotic vancomycin, which was first sold in 1954 and is widely available as a generic. In methicillin-susceptible staphylococcus aureus (MSSA) bacteremia, vancomycin has been associated with poor outcomes, including persistent bacteremia, treatment failure, and kidney toxicity. Moreover, vancomycin resistance is a growing problem, increasingly restricting its use.

"Right the first time" with broad-spectrum antibiotics improves outcomes

Bacteria can evolve rapidly as they divide and multiply in a short time, spreading throughout the body and causing damage, organ failure, and ultimately death if not treated adequately. It is, therefore, crucial to treat the patient "right the first time" by giving the right antibiotic that kills the causative pathogen on time. Studies in HABP show this has a marked impact on patient outcomes with a clinical improvement of 35% and a 12% increase in survival. However, identification of causative pathogens may take several days and is unsuccessful in 30-40% of the cases. Therefore, initial antibiotic therapy must be selected empirically. This means the physician should start therapy as soon as possible with a broad-spectrum antibiotic that covers resistant strains, to contain potential damage from the unknown causative pathogens.

Zevtera is well-positioned to become a standard treatment for hospital bacterial infections

We believe Zevtera is an excellent treatment option for difficult-to-treat patients with serious hospital bacterial infections, in particular when the involvement of Gram-positive pathogens, including Staphylococcus aureus, is suspected. Based on the positive phase III trials, Zevtera has a competitive and differentiated profile compared to in-market antibiotics, in various clinically important aspects, including a broad spectrum of activity against Gram-positive infections (including robust Gram-negative coverage) with strong bactericidal

activity against MSSA and MRSA, a low propensity for resistance development and a favorable kidney safety profile, in our view.

In MRSA pneumonia, treatment failure rates are high and have been attributed to inadequate initial therapy, emphasizing the value of “right the first time”. In addition, about one-third of all HABP patients are suspected of Pseudomonas infections. Zevtera exhibits potent activity against a number of Gram-positive and Gram-negative pathogens associated with hospital-acquired bacterial pneumonia (HABP) and community-acquired bacterial pneumonia (CABP). The drug combines the advantages of a cephalosporin with an enhanced Gram-positive spectrum, including bactericidal activity against MRSA, MRSE (methicillin-resistant Staphylococcus epidermidis), and PRSP (penicillin-resistant Streptococcus pneumoniae), while maintaining good activity against Gram-negative pathogens, including Pseudomonas and a fast onset of action. Importantly, this is combined with a good safety and tolerability profile. The simplicity of being a single agent could make it become a standard empiric treatment for hospital pneumonia.

Pneumonia first major Zevtera indication, with more to come

We have based our sales forecasts for Zevtera on its three major indications, including treating severe:

1) **Lung infections** (hospitalized CABP and HABP, excluding VABP)
2) **Bloodstream infections** (SAB – Staphylococcus aureus bacteremia)
3) **Skin infections** (ABSSSI – acute bacterial skin and skin structure infections)

In our detailed Zevtera forecasts, we have accounted for Basilea's commercialization plans with three distinctive regions, namely:

Europe/ROW (Europe distribution agreement with Advanz / ROW distributors)
China (CR Gosun – royalty agreement)
US (US commercialization partner to be announced before launch – we assume a royalty agreement).

Market exclusivity in EU/ROW should last through 2024, with extensions for new indications such as ABSSSI and bacteremia likely, while Zevtera should enjoy 10 years of US market exclusivity until 2033.

1) Lung infections – Risk-adjusted NPV of CHF 5 per share (page 33)

Europe/ROW: We believe peak product sales in Europe/ROW could amount to CHF 22 mn (or CHF 10 mn at transfer prices booked by Basilea), assuming a treatment price of CHF 1,800 per patient (assuming 10-day treatment, 3 vials per day at CHF 60 per vial) and CHF 900 (CHF 30 per vial) per patient in ROW distributor regions, with a penetration rate peaking at around 1-2% in Europe/ROW. With Advanz responsible for the distribution of Zevtera in Europe and Israel, Basilea sells product to Advanz at a transfer price. We assume the transfer price starts at 35% of the wholesale price and rises to 55% as Zevtera sales mature. Advanz makes its profit off the difference between wholesale and discounted transfer prices. Basilea benefits from selling Zevtera through an established distribution channel with no other costs than COGS and taxes.
China, Hong Kong, Macao: First launches by CR Gosun in 2023, with peak sales expected to reach CHF 47 mn. Our forecasts assume 12% royalties on sales and conservatively CHF 26 mn in development and sales milestones.

2) Severe bloodstream infections – Risk-adjusted NPV of CHF 12/share (page 34)

US: Assuming a US launch in mid-2024, peak product sales are expected to amount to CHF 205 mn based on a treatment price of USD 6,720 per patient with a peak penetration conservatively amounting to around 6% in 2033 (assuming Priority Review and approval Q2 2024), the last year before Zevtera loses its market exclusivity.

3) Severe skin infections – Risk-adjusted NPV of CHF 5 per share (page 35)

US: Assuming a US launch in mid-2024, peak sales are expected to amount to CHF 107 mn based on a treatment price of USD 2,240 per patient with a peak penetration of around 4%, with market exclusivity up to mid-2034.

Forecasts & Sensitivity Analysis

ZEVTERA (CEFTOBIPROLE) - FINANCIAL FORECASTS FOR BACTERIAL LUNG INFECTIONS

INDICATION	LUNG INFECTIONS (HOSPITAL AND COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA, EXCLUDING VENTILATOR-ASSOCIATED BACTERIAL PNEUMONIA (VABP))
DOSAGE	INTRAVENOUS INFUSION 3X DAILY 500 MG INFUSED OVER 2 HOURS FOR 7-14 DAYS (HOSPITAL ADMINISTERED PRODUCT)
PRICE	TREATMENT PRICE PER PATIENT (10 TREATMENT DAYS): EU: CHF 1,800 (10X CHF 180/DAY) I US: USD 2,400 (10X USD 240/DAY) I ROW: CHF 900 (10X CHF 90/DAY)
STANDARD OF CARE	CEPHALOSPORINS (CEFTAZIDIME), CARBEPENEMS (MEROPENEM), OXAZOLIDINONES (ZYVOX), ANTIBIOTIC COMBINATIONS (ZOSYN), QUINOLONES (CIPROFLOXACIN)
UNIQUE SELLING POINT	FIRST BROAD-SPECTRUM ANTI-MRSA* CEPHALOSPORIN APPROVED FOR BOTH HABP** AND CABP*** (EXCL. VABP) WITH GRAM-NEGATIVE COVERAGE, INCL. PSEUDOMONAS * MRSA = METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS; **HABP = HOSPITAL-ACQUIRED BACTERIAL PNEUMONIA; ***CABP = COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA

7Ps ANALYSIS

PATENT	EU: END 2024 = COMPOSITION OF MATTER (2019) + SPC (2024) + NEW US INDICATION (END 2023); US: 2033 = 5 YEARS NCE + 5 YEARS QIDP EXCLUSIVITY
PHASE	EU (DECENTRALIZED) APPROVAL IN 12 MEMBER STATES + SWITZERLAND FOR SEVERE PNEUMONIA TREATED IN HOSPITALS
PATHWAY	US: QUALIFIED INFECTIOUS DISEASE PRODUCT (QIDP) - CROSS-SUPPORTIVE PHASE III TRIAL CONSIDERED UNDER SPECIAL PROTOCOL ASSESSEMENT (SPA)
PATIENT	WELL-TOLERATED BROAD SPECTRUM HOSPITAL ANTIBIOTIC WITH GRAM-NEGATIVE PROPERTIES INCLUDING PSEUDOMONAS COVERAGE
PHYSICIAN	CAN BE USED EMPIRICALLY WITHOUT BACTERIAL PATHOGEN KNOWN DUE TO ITS BROAD SPECTRUM OF ACTIVITY
PAYER	HAS THE POTENTIAL TO LOWER HOSPITAL STAYS AND COSTS AND EXTENSIVE AND EXPENSIVE FOLLOW ON TREATMENT
PARTNER	CORE EU MARKETS: ADVANZ NOW RESPONSIBLE; DISTRIBUTORS FOR OTHER REGIONS AT TRANSFER PRICE; CR GOSUN RESPONSIBLE FOR CHINA, HONG KONG, MACAO

REVENUE MODEL

EUROPE / REST OF WORLD (ADVANZ/DISTRIBUTORS)	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E
NUMBER OF PATIENTS (MN)	1.8	1.8	1.8	1.9	1.9	1.9	2.0	2.0	2.0	2.1	2.1
GROWTH (%)	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
PATIENTS IN EUROPEAN MARKETS (MN)	0.7	0.7	0.7	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8
PENETRATION (%)	1%	1%	1%	1%	1%	0%	0%	0%	0%	0%	0%
NUMBER OF PATIENTS TREATED	5,128	6,297	7,500	5,709	4,346	3,309	2,519	1,917	1,460	1,111	846
COST OF THERAPY PER PATIENT (CHF)	1,800	1,800	1,800	1,800	1,800	1,800	1,800	1,800	1,800	1,800	1,800
SALES EUROPEAN MARKETS (CHF MN)	9	11	13	10	8	6	5	3	3	2	2
TRANSER PRICE FOR ADVANZ (%)	40%	45%	45%	45%	55%	55%	55%	55%	55%	55%	55%
SALES EUROPEAN MARKETS (CHF MN)	**4**	**5**	**6**	**5**	**4**	**3**	**2**	**2**	**1**	**1**	**1**
ROW PATIENTS IN DISTRIBUTOR REGIONS (MN)	1.1	1.1	1.1	1.1	1.1	1.2	1.2	1.2	1.2	1.2	1.2
PENETRATION (%)	0.5%	0.7%	0.8%	0.6%	0.5%	0.3%	0.3%	0.2%	0.1%	0.1%	0%
NUMBER OF PATIENTS TREATED	5,165	7,099	9,090	6,920	5,268	4,010	3,053	2,324	1,769	1,347	1,025
COST OF THERAPY PER PATIENT (CHF)	900	900	900	900	900	900	900	900	900	900	900
ROW SALES DISTRIBUTOR REGIONS (CHF MN)	5	6	8	6	5	4	3	2	2	1	1
TRANSFER PRICE (%)	40%	45%	45%	45%	55%	55%	55%	55%	55%	55%	55%
ROW SALES DISTRIBUTOR REGIONS (CHF MN)	**2**	**3**	**4**	**3**	**3**	**2**	**2**	**1**	**1**	**1**	**1**
SALES BOOKED BY BASILEA AT TRANSFER PRICE (CHF MN)	**6**	**8**	**10**	**7**	**7**	**5**	**4**	**3**	**2**	**2**	**1**
CHANGE (%)	49%	44%	22%	-24%	-7%	-24%	-24%	-24%	-24%	-24%	-24%
UPFRONT & MILESTONE PAYMENTS (CHF MN)	1										
COGS (CHF MN)	-2	-3	-3	-2	-2	-1	-1	-1	-1	0	0
SG&A (CHF MN)	-2	-2	-2	0	0	0	0	0	0	0	0
PROFIT BEFORE TAX (CHF MN)	**3**	**4**	**5**	**5**	**5**	**4**	**3**	**2**	**2**	**1**	**1**
TAX RATE (%)	0%	0%	0%	0%	20%	20%	20%	20%	20%	20%	20%
TAXES (CHF MN)	0	0	0	0	-1	-1	-1	0	0	0	0
PROFIT (CHF MN)	**3**	**4**	**5**	**5**	**4**	**3**	**2**	**2**	**1**	**1**	**1**

CHINA, HONG KONG, MACAO - CR GOSUN	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E
SALES (CHF MN)	**0**	**1**	**4**	**12**	**20**	**27**	**33**	**38**	**42**	**45**	**47**
ROYALTIES (~12%) (CHF MN)	0	0	0	1	2	3	4	5	5	5	6
UPFRONT & MILESTONE PAYMENTS (CHF MN)	0	0	3	0	5	0	6	0	6	0	6
PROFIT BEFORE TAX (CHF MN)	**0**	**0**	**3**	**1**	**7**	**3**	**10**	**5**	**11**	**5**	**12**
TAX RATE (%)	0%	0%	0%	0%	20%	20%	20%	20%	20%	20%	20%
TAXES (CHF MN)	0	0	0	0	-1	-1	-2	-1	-2	-1	-2
PROFIT (CHF MN)	**0**	**0**	**3**	**1**	**6**	**3**	**8**	**4**	**9**	**4**	**9**

	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E
GLOBAL SALES (CHF MN)	**14**	**19**	**26**	**29**	**33**	**37**	**40**	**44**	**46**	**48**	**49**
CHANGE (%)	36%	35%	37%	11%	14%	12%	10%	8%	6%	4%	3%
GLOBAL PROFIT (CHF MN)	**3**	**4**	**8**	**6**	**10**	**6**	**10**	**5**	**10**	**5**	**10**
CHANGE (%)	221%	38%	130%	-25%	59%	-43%	82%	-47%	88%	-47%	89%
WACC (%)	7%										
NPV TOTAL PROFIT (CHF MN)	**53**										
NUMBER OF SHARES (MN)	11.0										
NPV PER SHARE (CHF)	**5**										

SENSITIVITY ANALYSIS

		WACC (%)						
	CHF/SHARE	5.5	6.0	6.5	7.0	7.5	8.0	8.5
	110	11	11	11	11	6	10	10
	90	9	9	9	9	8	8	8
	70	7	7	7	7	7	6	6
PEAK PRODUCT SALES (CHF MN)	50	5	5	5	**5**	5	5	4
	30	3	3	3	3	3	3	3
	10	1	1	1	1	1	1	1

ESTIMATES AS OF 26 APRIL 2023

SOURCE: VALUATIONLAB ESTIMATES

ZEVTERA (CEFTOBIPROLE) - FINANCIAL FORECASTS FOR BACTEREMIA

INDICATION	STAPHYLOCOCCUS AUREUS BACTEREMIA (SEVERE BACTERIAL BLOOD STREAM INFECTION)
DOSAGE	INTRAVENOUS INFUSION 3X DAILY 500 MG INFUSED OVER 2 HOURS FOR ~21 DAYS (HOSPITAL ADMINISTERED PRODUCT)
PRICE	TREATMENT PRICE PER PATIENT (21 DAYS TREATMENT): US: USD 6,720 (21X USD 320/DAY)
STANDARD OF CARE	DAPTOMYCIN (BRANDED CUBICIN) AND VANCOMYCIN
UNIQUE SELLING POINT	BROAD-SPECTRUM ANTI-MRSA* CEPHALOSPORIN FOR TREATING STAPHYLOCOCCUS AUREUS BACTEREMIA * MRSA = METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS; ** SPC = SUPPLEMENTARY PROTECTION CERTIFICATE

7Ps ANALYSIS

PATENT	EU: END 2024 = COMPOSITION OF MATTER (2019) + ** SPC (2024) + NEW US INDICATION (END 2023); US: 2033 = 5 YEARS NCE + 5 YEARS QIDP EXCLUSIVITY
PHASE	PHASE III "ERADICATE" TRIAL STARTED AUG 2018; POSITIVE RESULTS JUN 2022; US NDA FILING Q3 2023; APPROVAL Q2 2024; US LAUNCH MID 2024
PATHWAY	US: QUALIFIED INFECTIOUS DISEASE PRODUCT (QIDP) - CROSS-SUPPORTIVE PHASE III TRIAL CONSIDERED UNDER SPECIAL PROTOCOL ASSESSEMENT (SPA)
PATIENT	EFFECTIVE AND WELL-TOLERATED HOSPITAL ANTIBIOTIC WITH ANTI-MRSA PROPERTIES
PHYSICIAN	CAN BE USED EMPIRICALLY WITHOUT BACTERIAL PATHOGEN KNOWN DUE TO ITS BROAD SPECTRUM OF ACTIVITY
PAYER	HAS THE POTENTIAL TO LOWER HOSPITAL STAYS AND COSTS AND EXTENSIVE AND EXPENSIVE FOLLOW ON TREATMENT
PARTNER	US: US PHASE III DEVELOPMENT CAN START WITH BARDA FUNDING, US COMMERCIALIZATION PARTNER WILL FOLLOW LATER; EU/ROW: SAME PARTNERS AS IN HCAP

REVENUE MODEL

UNITED STATES (PARTNER TO BE ANNOUNCED)	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**	**2029E**	**2030E**	**2031E**	**2032E**
NUMBER OF PATIENTS (MN)	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.6
GROWTH (%)	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
PENETRATION (%)	0%	0%	1%	3%	5%	6%	6%	6%	6%	6%	3%
NUMBER OF PATIENTS TREATED	0	0	3,942	14,503	22,842	28,336	31,376	33,174	33,671	34,176	19,079
COST OF THERAPY PER PATIENT (CHF)	6,294	6,058	6,001	6,001	6,001	6,001	6,001	6,001	6,001	6,001	6,001
PARTNER SALES (CHF MN)	**0**	**0**	**24**	**87**	**137**	**170**	**188**	**199**	**202**	**205**	**114**
CHANGE (%)				268%	58%	24%	11%	6%	1%	1%	-44%
ROYALTY (%)	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
ROYALTIES (CHF MN)	0	0	5	17	27	34	38	40	40	41	23
UPFRONT & MILESTONE PAYMENTS (CHF MN)	0	5	0	4	0	9	0	0	0	11	0
R&D COSTS (CHF MN)	-5	-2	0	0	0	0	0	0	0	0	0
PROFIT BEFORE TAX (USD MN)	**-5**	**3**	**5**	**24**	**31**	**48**	**42**	**45**	**45**	**58**	**26**
TAXES (CHF MN)	0	0	0	0	-5	-9	-8	-8	-8	-10	-5
PROFIT (CHF MN)	**-5**	**3**	**5**	**22**	**22**	**34**	**30**	**32**	**32**	**41**	**18**

	2022E	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**	**2029E**	**2030E**	**2031E**	**2032E**
GLOBAL SALES (CHF MN)	**0**	**0**	**24**	**87**	**137**	**170**	**188**	**199**	**202**	**205**	**114**
CHANGE (%)				268%	58%	24%	11%	6%	1%	1%	-44%
GLOBAL PROFIT (CHF MN)	**-5**	**3**	**5**	**22**	**22**	**34**	**30**	**32**	**32**	**41**	**18**
CHANGE (%)	4%	-158%	75%	362%	0%	57%	-12%	6%	1%	28%	-56%

WACC (%)	7%	
NPV TOTAL PROFIT (CHF MN)	**160**	
NUMBER OF SHARES (MN)	11.0	
NPV PER SHARE (CHF)	**15**	
SUCCESS PROBABILITY	80%	(FILING SUCCESS RATE)
RISK ADJUSTED NPV PER SHARE (CHF)	**12**	

SENSITIVITY ANALYSIS

		WACC (%)						
	CHF/SHARE	5.5	6.0	6.5	7.0	7.5	8.0	8.5
	100%	16	15	15	15	14	14	13
	95%	15	15	14	14	13	13	13
	90%	14	14	13	13	13	12	12
	85%	13	13	13	12	12	12	11
SUCCESS PROBABILITY	80%	13	12	12	**12**	11	11	11
	75%	12	12	11	11	11	10	10
	70%	11	11	10	10	10	10	9
	65%	10	10	10	9	9	9	9
	60%	10	9	9	9	9	8	8

ESTIMATES AS OF 26 APRIL 2023

SOURCE: VALUATIONLAB ESTIMATES

ZEVTERA (CEFTOBIPROLE) - FINANCIAL FORECASTS FOR SEVERE SKIN INFECTIONS

INDICATION	ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS (ABSSSI) INCLUDING MRSA* PATHOGENS
DOSAGE	INTRAVENOUS INFUSION 3X DAILY 500 MG INFUSED OVER 2 HOURS FOR 5-10 DAYS (HOSPITAL ADMINISTERED PRODUCT)
PRICE	TREATMENT PRICE PER PATIENT (7 DAYS TREATMENT): US: USD 2,240 (7X USD 320/DAY)
STANDARD OF CARE	CEPHALOSPORINS (CEFTAZIDIME), CARBEPENEMS (MEROPENEM), OXAZOLIDINONES (ZYVOX), ANTIBIOTIC COMBINATIONS (ZOSYN), QUINOLONES (CIPROFLOXIN)
UNIQUE SELLING POINT	BROAD-SPECTRUM ANTI-MRSA* CEPHALOSPORIN INCLUDING GRAM NEGATIVE COVERAGE FOR TREATING ABSSSI * MRSA = METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS; ** SPC = SUPPLEMENTARY PROTECTION CERTIFICATE

7Ps ANALYSIS

PATENT	EU: END 2024 = COMPOSITION OF MATTER (2019) + ** SPC (2024) + NEW US INDICATION (END 2023); US: 2033 = 5 YEARS NCE + 5 YEARS QIDP EXCLUSIVITY
PHASE	POSITIVE TOPLINE RESULTS PHASE III "TARGET" TRIAL AUG 2019; US NDA FILING Q3 2023; APPROVAL Q2 2024; LAUNCH MID 2024
PATHWAY	US: QUALIFIED INFECTIOUS DISEASE PRODUCT (QIDP) - CROSS-SUPPORTIVE PHASE III TRIAL CONSIDERED UNDER SPECIAL PROTOCOL ASSESSEMENT (SPA)
PATIENT	EFFECTIVE AND WELL-TOLERATED HOSPITAL ANTIBIOTIC WITH ANTI-MRSA PROPERTIES
PHYSICIAN	CAN BE USED EMPIRICALLY WITHOUT BACTERIAL PATHOGEN KNOWN DUE TO ITS BROAD SPECTRUM OF ACTIVITY
PAYER	HAS THE POTENTIAL TO LOWER HOSPITAL STAYS AND COSTS AND EXTENSIVE AND EXPENSIVE FOLLOW ON TREATMENT
PARTNER	US: US PHASE III DEVELOPMENT CAN START WITH BARDA FUNDING, US COMMERCIALIZATION PARTNER WILL FOLLOW LATER; EU/ROW: SAME PARTNERS AS IN HAP/CAP

REVENUE MODEL

UNITED STATES - (PARTNER TO BE ANNOUNCED)	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**	**2029E**	**2030E**	**2031E**	**2032E**
NUMBER OF PATIENTS (MN)	1.2	1.2	1.2	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.4
GROWTH (%)	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
PENETRATION (%)	0%	0%	1%	2%	2%	3%	3%	4%	4%	4%	1%
NUMBER OF PATIENTS TREATED	0	0	9'854	18'753	25'380	32'201	39'220	46'443	49'834	53'315	17'587
COST OF THERAPY PER PATIENT (CHF)	2'098	2'019	2'000	2'000	2'000	2'000	2'000	2'000	2'000	2'000	2'000
PARTNER SALES (CHF MN)	**0**	**0**	**20**	**38**	**51**	**64**	**78**	**93**	**100**	**107**	**35**
CHANGE (%)				90%	35%	27%	22%	18%	7%	7%	-67%
ROYALTY (%)	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
ROYALTIES (CHF MN)	0	0	4	8	10	13	16	19	20	21	7
UPFRONT & MILESTONE PAYMENTS (CHF MN)	0	4	0	0	0	4	0	0	0	9	0
R&D COSTS (CHF MN)	-1	-1	0	0	0	0	0	0	0	0	0
PROFIT BEFORE TAX (USD MN)	**-1**	**3**	**4**	**8**	**11**	**19**	**18**	**21**	**22**	**34**	**8**
TAXES (CHF MN)	0	0	0	0	-2	-3	-3	-4	-4	-6	-1
PROFIT (CHF MN)	**-1**	**3**	**4**	**8**	**8**	**14**	**13**	**15**	**16**	**24**	**6**

	2022E	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**	**2029E**	**2030E**	**2031E**	**2032E**
GLOBAL SALES (CHF MN)	**0**	**0**	**20**	**38**	**51**	**64**	**78**	**93**	**100**	**107**	**35**
CHANGE (%)				90%	35%	27%	22%	18%	7%	7%	-67%
GLOBAL PROFIT (CHF MN)	**-1**	**3**	**4**	**8**	**8**	**14**	**13**	**15**	**16**	**24**	**6**
CHANGE (%)		-389%	46%	90%	8%	71%	-10%	18%	7%	52%	-77%

WACC (%)	7%	
NPV TOTAL PROFIT (CHF MN)	**73**	
NUMBER OF SHARES (MN)	11.0	
NPV PER SHARE (CHF)	**7**	
SUCCESS PROBABILITY	80%	(FILING SUCCESS RATE)
RISK ADJUSTED NPV PER SHARE (CHF)	**5**	

SENSITIVITY ANALYSIS

		WACC (%)						
	CHF/SHARE	5.5	6.0	6.5	7.0	7.5	8.0	8.5
	100%	7	7	7	7	6	6	6
	95%	7	7	6	6	6	6	6
	90%	6	6	6	6	6	6	6
	85%	6	6	6	6	5	5	5
SUCCESS PROBABILITY	80%	6	6	5	**5**	5	5	5
	75%	5	5	5	5	5	5	5
	70%	5	5	5	5	5	4	4
	65%	5	5	4	4	4	4	4
	60%	4	4	4	4	4	4	4

ESTIMATES AS OF 26 APRIL 2023

SOURCE: VALUATIONLAB ESTIMATES

Unique Selling Point

Zevtera provides physicians with a first-line simplified empiric treatment option in patients with community-acquired bacterial pneumonia (CABP) and hospital-acquired bacterial pneumonia (HABP), excluding ventilator-associated bacterial pneumonia (VABP), with its broad-spectrum of activity, potentially reducing the need for current combination antibiotic therapy. Potential to treat bacteremia and severe bacterial skin infections.

7P's Analysis

Patent: Zevtera enjoys exclusivity until at least 2024 in the EU consisting of a composition of matter patent (2019) and SPC extension (5 years). With the QIDP designation, Zevtera is eligible for five years of market exclusivity in addition to the five years of NCE (new chemical entity) exclusivity granted for a newly approved product in the US. Zevtera received the designation for community-acquired bacterial pneumonia, Staphylococcus aureus bacteremia (SAB), and acute bacterial skin and skin structure infections (ABSSSI).

Phase: Zevtera is approved in thirteen European countries for treating CABP and HABP, excluding VABP, in adults. In 2015 the drug was launched first in Germany, followed by Austria, Switzerland, the UK, and France. Italy, and Spain. Currently, Zevtera has been launched in 20 countries globally. Basilea expects to file an NDA for US approval in three indications (SAB, ABSSSI, and CABP) in Q3 2023, with a US approval in Q2 2024.

Pathway: In April 2017, Basilea gained Special Protocol Assessment (SPA) for the cross-supportive phase III trial protocols for ABSSSI ("TARGET" trial, positive results reported in August 2019), and SAB ("ERADICATE" trial, positive results reported in June 2022), both required for US approval. The BARDA agreement secured approximately 70% of the necessary co-funding.

Patient: Zevtera is a well-tolerated broad-spectrum antibiotic with proven efficacy in SAB, ABSSSI, and CABP, particularly in patients with MRSA and high-risk patients, enabling to treat these vulnerable patients effectively early in their disease to achieve recovery.

Physician: Zevtera provides physicians with a first-line simplified empiric treatment option in patients with hospital-acquired pneumonia with its broad-spectrum activity, potentially reducing the need for current combination antibiotic therapy.

Payer: Treating "right the first time" improves outcomes considerably thereby reducing costly hospital stays or the need for follow-on therapy. A post hoc analysis of the phase III HABP trial showed Zevtera was able to reduce ICU stay by an average of 3 days and hospital stay by 2 days.

Partner: Advanz has commercialization rights for Zevtera in Europe (excl. the Nordics) and Israel, and CR Gosun in China, Hong Kong, and Macao. In other countries/regions, the company has entered into distribution agreements for MENA, Latin America, Canada, the Nordics, Russia, and the Eurasian Economic Union with distributors. We assume Basilea sells Zevtera at a distributor transfer price starting at 35% of the wholesale price in the first years of launch and up to 55% in the later years, except for CR Gosun, where it receives development and sales milestones and an estimated ~12 royalties on net sales. We assume Basilea to contract a US commercialization partner before US FDA approval.

Income Statement

BASILEA PHARMACEUTICA									SHARE PRICE (CHF)	42.5	
US GAAP											
INCOME STATEMENT (CHF MN)	**2022**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**	**2029E**	**2030E**	**2031E**	**2032E**
PRODUCT SALES (INCLUDING PARTNER SALES)	**365**	**453**	**583**	**746**	**886**	**898**	**653**	**614**	**595**	**561**	**397**
CHANGE (%)	16%	24%	29%	28%	19%	1%	-27%	-6%	-3%	-6%	-29%
PRODUCT REVENUE (BOOKED BY BASILEA)	**33**	**33**	**28**	**32**	**37**	**35**	**16**	**8**	**4**	**3**	**2**
CHANGE (%)	25%	2%	-15%	16%	13%	-4%	-54%	-51%	-46%	-40%	-35%
CONTRACT REVENUE (INCL. MILESTONES & ROYALTIES)	**90**	**115**	**106**	**173**	**161**	**218**	**116**	**123**	**114**	**141**	**95**
CHANGE (%)	-15%	28%	-7%	63%	-7%	35%	-47%	6%	-8%	24%	-33%
1) ROYALTIES & MILESTONES (FROM PARTNERS)	**88**	**113**	**105**	**171**	**160**	**217**	**115**	**122**	**113**	**140**	**94**
CHANGE (%)	-14%	28%	-8%	64%	-7%	36%	-47%	6%	-8%	24%	-33%
2) DEFERRED REVENUES IN CONTRACT REVENUE:	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**1**
OTHER REVENUES	**25**	**5**	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**
+ REVENUE FROM R&D SERVICES	0	0	0	0	0	0	0	0	0	0	0
+ OTHER REVENUE:	25	5	2	2	2	2	2	2	2	2	2
+ BARDA REVENUE	8	0	0	0	0	0	0	0	0	0	0
+ MILESTONES ONCOLOGY ASSET TRANSACTIONS	15	3									
+ OTHERS	2	2	2	2	2	2	2	2	2	2	2
TOTAL REVENUES (EXCL. PARTNER SALES)	**148**	**152**	**136**	**207**	**200**	**256**	**135**	**133**	**120**	**146**	**99**
CHANGE (%)	0%	3%	-11%	52%	-3%	28%	-47%	-1%	-10%	21%	-32%
COGS	**-25**	**-28**	**-18**	**-18**	**-19**	**-18**	**-14**	**-12**	**-11**	**-11**	**-10**
CHANGE (%)	2%	13%	-35%	2%	3%	-6%	-24%	-13%	-7%	-4%	-2%
GROSS PROFIT	**123**	**125**	**118**	**189**	**181**	**238**	**121**	**121**	**109**	**135**	**88**
CHANGE (%)	-1%	1%	-5%	60%	-4%	31%	-49%	0%	-10%	23%	-35%
MARGIN (%)	83%	82%	87%	91%	90%	93%	90%	91%	91%	93%	89%
R&D	**-74**	**-53**	**-52**	**-53**	**-53**	**-54**	**-54**	**-55**	**-55**	**-56**	**-50**
CHANGE (%)	-21%	-28%	-1%	1%	1%	1%	1%	1%	1%	1%	-11%
S,G&A	**-31**	**-27**	**-27**	**-25**	**-25**	**-25**	**-26**	**-26**	**-26**	**-26**	**-27**
CHANGE (%)	4%	-13%	0%	-5%	0%	0%	1%	1%	1%	1%	1%
OPERATING EXPENSES (INCL. COGS)	**-129**	**-108**	**-97**	**-97**	**-98**	**-97**	**-94**	**-93**	**-93**	**-93**	**-87**
CHANGE (%)	-12%	-17%	-10%	-1%	1%	0%	-4%	-1%	0%	0%	-7%
PROFIT FROM SALE OF ASSETS											
EBIT	**19**	**45**	**39**	**111**	**102**	**158**	**41**	**41**	**28**	**52**	**12**
CHANGE (%)	1461%	142%	-13%	184%	-7%	54%	-74%	0%	-32%	90%	-77%
MARGIN (%)	12.5%	29.4%	28.6%	53.4%	51.2%	62.0%	30.4%	30.5%	23.0%	36.1%	12.1%
EBITDA	**20**	**46**	**40**	**112**	**104**	**160**	**43**	**43**	**30**	**55**	**15**
CHANGE (%)	911%	135%	-13%	178%	-7%	54%	-73%	0%	-30%	83%	-73%
MARGIN (%)	13.3%	30.2%	29.6%	54.1%	52.0%	62.6%	31.8%	32.1%	25.0%	37.8%	15.0%
D&A	**1**	**1**	**1**	**1**	**2**	**2**	**2**	**2**	**2**	**3**	**3**
NET INTEREST INCOME/(EXPENSE)	**-10**	**-13**	**-11**	**-4**	**-4**	**-4**	**0**	**0**	**0**	**0**	**0**
NET OTHER FINANCIAL INCOME/(EXPENSES)	**1**	**1**	**1**	**2**	**2**	**3**	**4**	**5**	**6**	**8**	**9**
LOSSES FROM SENIOR UNSECURED BOND TRANSACTIONS	0										
OTHER COMPONENTS OF NET PERIODIC PENSION COST	2	2	2	2	2	2	2	2	2	2	2
PROFIT BEFORE TAXES	**12**	**35**	**32**	**111**	**104**	**160**	**47**	**48**	**36**	**63**	**24**
CHANGE (%)	-278%	193%	-10%	247%	-7%	55%	-70%	2%	-24%	72%	-62%
MARGIN (%)	8%	23%	23%	54%	52%	63%	35%	36%	30%	43%	24%
TAXES	**0**	**0**	**0**	**0**	**-38**	**-49**	**-25**	**-26**	**-23**	**-28**	**-16**
NET PROFIT/LOSS	**12**	**35**	**32**	**111**	**66**	**111**	**22**	**23**	**13**	**34**	**7**
CHANGE (%)	-278%	192%	-10%	247%	-41%	69%	-80%	3%	-42%	160%	-79%
MARGIN (%)	8%	23%	24%	54%	33%	44%	16%	17%	11%	24%	7%
EPS (CHF)	**1.02**	**2.97**	**2.68**	**9.29**	**5.52**	**9.31**	**1.83**	**1.88**	**1.10**	**2.87**	**0.62**

ESTIMATES AS OF 26 APRIL 2023

SOURCE: VALUATIONLAB ESTIMATES

BASILEA FY 2023 GUIDANCE

(IN CHF MN)	FY 2023 GUIDANCE
+ PRODUCT REVENUE	-
+ CONTRACT REVENUE	-
+ REVENUE FROM R&D SERVICES	-
+ OTHER REVENUE (E.G., BARDA, ONCOLOGY TRANSACTIONS)	-
TOTAL REVENUE:	**155 - 158**
OF WHICH CRESEMBA & ZEVTERA RELATED REVENUE	145 - 148
OF WHICH ROYALTY INCOME	~74
- COST OF GOODS SOLD	25 - 28
- RESEARCH AND DEVELOPMENT EXPENSES	-
- SELLING, GENERAL & ADMINISTRATIVE EXPENSES	-
OPERATING EXPENSES (EX. COGS)	~80
OPERATING RESULT	**45 - 50**
NET RESULT	**36 - 41**
CASH AND CASH EQUIVALENTS (31 DECEMBER)	**-**

SOURCE: BASILEA PHARMACEUTICA, VALUATIONLAB

Total Revenues – Breakdown

BASILEA PHARMACEUTICA									SHARE PRICE (CHF)	42.5	
US GAAP											
INCOME STATEMENT (CHF MN)	**2022**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**	**2029E**	**2030E**	**2031E**	**2032E**
PRODUCT SALES (INCLUDING PARTNER SALES)	**365**	**453**	**583**	**746**	**886**	**898**	**653**	**614**	**595**	**561**	**397**
CHANGE (%)	16%	24%	29%	28%	19%	1%	-27%	-6%	-3%	-6%	-29%
PRODUCT REVENUE (BOOKED BY BASILEA)	**33**	**33**	**28**	**32**	**37**	**35**	**16**	**8**	**4**	**3**	**2**
CHANGE (%)	25%	2%	-15%	16%	13%	-4%	-54%	-51%	-46%	-40%	-35%
CONTRACT REVENUE (INCL. MILESTONES & ROYALTIES)	**90**	**115**	**106**	**173**	**161**	**218**	**116**	**123**	**114**	**141**	**95**
CHANGE (%)	-15%	28%	-7%	63%	-7%	35%	-47%	6%	-8%	24%	-33%
1) ROYALTIES & MILESTONES (FROM PARTNERS)	**88**	**113**	**105**	**171**	**160**	**217**	**115**	**122**	**113**	**140**	**94**
CHANGE (%)	-14%	28%	-8%	64%	-7%	36%	-47%	6%	-8%	24%	-33%
A) CRESEMBA ROYALTY REVENUES (TOTAL)	**88**	**105**	**93**	**141**	**115**	**153**	**52**	**59**	**41**	**52**	**52**
+ PFIZER ROYALTY REVENUE (~16%)	22	28	35	43	50	50	33	28	27	28	30
+ PFIZER MILESTONES (EU/RUS/TRK/ISR)	1	5	0	8	0	8	0	4	0	0	0
+ PFIZER MILESTONES (CHINA/HK/MACAO)	0	5	0	5	0	7	0	9	0	20	21
+ ASTELLAS ROYALTY REVENUE (TIERED)	43	45	48	51	54	44	9	2	0	0	0
+ ASTELLAS MILESTONES (DIRECT)	20	14	0	27	0	36	0	0	0	0	0
+ ASAHI KASEI ROYALTY REVENUE (~12%)	0	4	5	7	8	9	10	11	9	3	1
+ ASAHI MILESTONES (DIRECT)	2	5	4	0	4	0	0	6	5	2	0
B) ZEVTERA ROYALTY REVENUE (TOTAL)	**0**	**8**	**12**	**31**	**45**	**64**	**63**	**63**	**71**	**87**	**42**
+ CR GOSUN ROYALTY REVENUE (~12%)	0	0	0	1	2	3	4	5	5	5	6
+ CR GOSUN MILESTONES (DIRECT)	0	0	3	0	5	0	6	0	6	0	6
+ US PARTNER (TBD) ABSSSI ROYALTY REVENUE (~20%)	0	0	4	8	10	13	16	19	20	21	7
+ US PARTNER (TBD) MILESTONES (DIRECT)	0	4	0	0	0	4	0	0	0	9	0
+ US PARTNER (TBD) SAB ROYALTY REVENUE (~20%)	0	0	5	17	27	34	38	40	40	41	23
+ US PARTNER (TBD) MILESTONES (DIRECT)	0	5	0	4	0	9	0	0	0	11	0
2) DEFERRED REVENUES IN CONTRACT REVENUE:	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**1**
OTHER REVENUES	**25**	**5**	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**
+ REVENUE FROM R&D SERVICES	0	0	0	0	0	0	0	0	0	0	0
+ OTHER REVENUE:	25	5	2	2	2	2	2	2	2	2	2
+ BARDA REVENUE	8	0	0	0	0	0	0	0	0	0	0
+ MILESTONES ONCOLOGY ASSET TRANSACTIONS	15	3									
+ OTHERS	2	2	2	2	2	2	2	2	2	2	2
TOTAL REVENUES (EXCL. PARTNER SALES)	**148**	**152**	**136**	**207**	**200**	**256**	**135**	**133**	**120**	**146**	**99**
CHANGE (%)	0%	3%	-11%	52%	-3%	28%	-47%	-1%	-10%	21%	-32%

Breakdown of Basilea's Total Revenues.
Basilea follows US GAAP accounting, where upfront milestones are typically deferred over the contract period, while sales milestones are generally booked when received.

Total Revenues consist of Product Revenues (booked by Basilea), Royalties (from Partners), Contract Revenue (including Milestones), and Other Revenues (Revenues from R&D Services + Other Income (e.g., BARDA reimbursement and proceeds from oncology transactions).

In Contract Revenue (including Milestones), we provide a breakdown of Deferred Revenues in Contract Revenue according to the various license and distribution agreements Basilea has signed with third parties.

Ratios I Balance Sheet I Cash Flow Statement

BASILEA PHARMACEUTICA									SHARE PRICE (CHF)	42.5
US GAAP										
RATIOS	**2022**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**	**2029E**	**2030E**	**2031E**	**2032E**
P/E		14.3x	15.9x	4.6x	7.7x	4.6x	23.3x	22.6x	38.6x	14.8x	69.0x
P/S		3.3x	3.7x	2.5x	2.5x	2.0x	3.8x	3.8x	4.2x	3.5x	5.1x
P/NAV		-19.0x	-16.0x	6.3x	3.4x	3.1x	2.7x	2.4x	2.3x	1.9x	1.9x
EV/EBITDA		6.6x	7.6x	2.7x	2.9x	1.9x	7.1x	7.1x	10.1x	5.5x	20.6x
PER SHARE DATA (CHF)	**2022**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**	**2029E**	**2030E**	**2031E**	**2032E**
EARNINGS	**1.02**	**2.97**	**2.68**	**9.29**	**5.52**	**9.31**	**1.83**	**1.88**	**1.10**	**2.87**	**0.62**
CHANGE (%)	-275%	190%	-10%	247%	-41%	69%	-80%	3%	-42%	160%	-79%
CASH	**9.15**	**8.58**	**8.15**	**17.57**	**23.23**	**24.31**	**26.30**	**28.37**	**29.66**	**32.75**	**33.60**
CHANGE (%)	-29%	-6%	-5%	115%	32%	5%	8%	8%	5%	10%	3%
DIVIDENDS	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**
PAYOUT RATIO (%)	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
NET ASSET VALUE	**-1.75**	**-2.24**	**-2.66**	**6.75**	**12.41**	**13.50**	**15.49**	**17.55**	**18.85**	**21.93**	**22.79**
CHANGE (%)	-65%	28%	19%	-354%	84%	9%	15%	13%	7%	16%	4%
BALANCE SHEET (CHF MN)	**2022**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**	**2029E**	**2030E**	**2031E**	**2032E**
NET LIQUID FUNDS	**109**	**103**	**97**	**210**	**278**	**291**	**314**	**339**	**355**	**391**	**402**
TOTAL ASSETS	**221**	**215**	**210**	**322**	**390**	**403**	**427**	**451**	**467**	**504**	**514**
FINANCIAL DEBT	**132**	**132**	**95**	**95**	**95**	**0**	**0**	**0**	**0**	**0**	**0**
AS PERCENTAGE OF TOTAL ASSETS (%)	60%	62%	45%	29%	24%	0%	0%	0%	0%	0%	0%
TOTAL SHAREHOLDERS' EQUITY	**-21**	**-27**	**-32**	**81**	**148**	**161**	**185**	**210**	**225**	**262**	**272**
CHANGE (%)											
RETURN ON EQUITY (%)	-59%	-133%	-101%	138%	45%	69%	12%	11%	6%	13%	3%
EMPLOYEES	141	141	142	144	145	147	148	150	151	153	154
CHANGE (%)	15%	0%	1%	1%	1%	1%	1%	1%	1%	1%	1%
CASH FLOW STATEMENT (CHF MN)	**2022**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**	**2029E**	**2030E**	**2031E**	**2032E**
NET PROFIT / (LOSS)	**12**	**35**	**32**	**111**	**66**	**111**	**22**	**23**	**13**	**34**	**7**
DEPRECIATION & AMORTIZATION	1	1	1	1	2	2	2	2	2	3	3
OTHER NON-CASH ITEMS	-12	0	0	0	0	0	0	0	0	0	0
NET CASH FLOW FROM OPERATING ACTIVITIES	**7**	**37**	**33**	**113**	**68**	**113**	**24**	**25**	**16**	**37**	**10**
NET CASH FLOW FROM INVESTING ACTIVITIES	**92**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
NET CASH FLOW USED IN OPERATING ACTIVITIES	**99**	**38**	**33**	**113**	**68**	**113**	**24**	**25**	**16**	**37**	**10**
NET CASH FLOWS FROM FINANCING ACTIVITIES	-45	-44	-38	0	0	-100	0	0	0	0	0
FX RATE CHANGES ON CASH AND CASH EQUIVALENTS	0										
NET CHANGE IN CASH & CASH EQUIVALENTS	**54**	**-6**	**-5**	**113**	**68**	**13**	**24**	**25**	**16**	**37**	**10**
ESTIMATES AS OF 26 APRIL 2023									SOURCE: VALUATIONLAB ESTIMATES		

NOTE: With gross cash (including reserved cash) of CHF 108.6 mn (31 December 2022), increasing revenues from Cresemba in invasive fungal infections, and Zevtera in severe bacterial lung infections (EU/ROW), Basilea has sufficient cash to execute its development plans while remaining profitable, in our view.

APPENDIX

BASILEA ADDITIONAL DATA & DISEASE MARKETS

I) Money raised:

Since Basilea was spun-off from Roche in 2000, the company has raised almost CHF 1.1 bn. Roche provided an initial capital contribution of CHF 206 mn, next to several compounds. In 2003 Basilea raised CHF 21 mn in a private placement ahead of the IPO in 2004 where the company raised another CHF 193 mn. A secondary offering in 2007 resulted in net proceeds of CHF 310 mn.

MONEY RAISED	CHF MN
PRE-IPO	206
IPO (INITIAL PUBLIC OFFERING)	193
PRIVATE PLACEMENTS / SECONDARY OFFERINGS	377
CONVERTIBLE BONDS	297
TOTAL RAISED	**1,072**

SOURCE: VALUATIONLAB ESTIMATES, BASILEA PHARMACEUTICA

The cash was used primarily related to the company's operating activities, especially the research and development programs, as well as for the buildup of its past commercialization organization. Basilea repaid capital of CHF 48 mn (CHF 5 per share) to shareholders in June 2013. Importantly, Basilea succeeded in fully developing three products up to commercialization, including Toctino, launched in 2009; Zevtera, launched in 2014; and Cresemba, launched in 2015.

In December 2015, Basilea successfully placed a CHF 200 mn senior unsecured convertible bond with an annual coupon of 2.75% (payable semi-annually in arrear with maturity in December 2022). The proceeds, together with cash on hand, were used to 1) participate in a US phase III development program for Zevtera, 2) support and expand the commercialization of Cresemba and Zevtera, 3) support post-approval pediatric studies for Cresemba and Zevtera in Europe, 4) advance the oncology pipeline candidates.

In July 2020, Basilea improved its debt maturity profile through the combined transaction of issuing a new CHF 97 mn senior unsecured convertible bond (annual coupon of 3.25% payable semi-annually in arrear with maturity in July 2027) and executing a partial repurchase of CHF 47 mn of the previous CHF 200 mn convertible bond with maturity in 2022. As a result, about 25% of the debt has been extended from 2022 to 2027, providing the company with financial flexibility to execute its mid-term growth strategy. Basilea has earmarked the majority of the CHF 50 mn cash inflow from the July 2020 convertible bond transaction to further reduce the mid-term debt by about a further 25% in the next 2 years.

In February 2021, CHF 45.75 mn gross proceeds were raised in a private placement of 1 mn new registered shares (8.4% of Basilea's issued share capital) of CHF 1.00 par value each at CHF 45.75 per new share.

In September 2022, Basilea closed a CHF 75 mn senior secured loan agreement with Athyrium Capital Management, LP. The loan was used for the non-dilutive repayment of the

convertible bonds due on 23 December 2022 with an outstanding nominal amount of CHF 113.8 mn, with the remainder paid with cash at hand. The loan has a two-year term with repayment to start in Q1 2023 every quarter. Interest payments, excluding fees, are estimated at approximately CHF 1.25 mn per quarter of the term.

II) Partnerships:

In 2010, Basilea signed its first major partnership for Cresemba with Astellas Pharmaceuticals to develop and commercialize the hospital antifungal in the US, followed in 2016 by Asahi Kasei Pharma (Japan) and in 2017 by Pfizer in Europe (excluding the Nordics), Russia, Turkey, and Israel, which extended the agreement for Cresemba to China, Hong Kong, Macao and 16 other countries in the Asia Pacific Region in early 2018. The partnership with Pfizer effectively replaced the prior contract sales force provided by Quintiles, which initially sold Cresemba and Zevtera in the major European markets. CR Gosun acquired the development and commercialization rights for Zevtera in 2017.

LICENSE PARTNERS	PRODUCT(S)	COUNTRIES COVERED	SIGNING DATE	UPFRONT PAYMENT	MILESTONES (RECEIVED)	MILESTONES (OUTSTANDING)	ROYALTIES ON SALES
ASTELLAS	CRESEMBA	UNITED STATES OF AMERICA	FEB 2010	CHF 75 MN	CHF 72 MN: - CHF 42 MN REGULATORY - CHF 50 MN SALES	CHF 240 MN	TIERED MID-TEENS TO MID-TWENTIES
ASAHI KASEI PHARMA	CRESEMBA	JAPAN	SEP 2016	CHF 7 MN	CHF 5 MN	CHF 55 MN	DOUBLE DIGIT TIERED
PFIZER	CRESEMBA	1) EUROPE (EXCL. THE NORDICS), RUSSIA, TURKEY & ISRAEL; 2) EXTENSION TO INCLUDE CHINA, HONG KONG, MACAO & 16 COUNTRIES ASIA PACIFIC REGION	1) JUL 2017 2) JAN 2018	USD 73 MN	USD 49.3 MN: - USD 16 MN REGULATORY - USD 33.3 MN SALES	USD 600 MN	MID-TEEN
CR GOSUN	ZEVTERA	CHINA, HONG KONG, MACAO	SEP 2017	CHF 3 MN	CHF 3 MN	CHF 142 MN	DOUBLE-DIGIT TIERED

DISTRIBUTION PARTNERS	PRODUCT(S)	COUNTRIES COVERED	SIGNING DATE	UPFRONT PAYMENT	MILESTONES (RECEIVED)	MILESTONES (OUTSTANDING)	PRICING
HIKMA	CRESEMBA ZEVTERA	MIDDLE EAST AND NORTH AFRICA (MENA REGION)	OCT 2015 (ZEVTERA) AUG 2016 (CRESEMBA)	CHF 1 MN (ZEVTERA) UNDISCLOSED (CRESEMBA)	--	UNDISCLOSED	BASILEA SELLS PRODUCT(S) AT TRANSFER PRICE
KNIGHT THERAPEUTICS (FORMERLY GRUPO BIOTOSCANA)	CRESEMBA ZEVTERA	19 COUNTRIES IN LATIN AMERICA INCL. BRAZIL, MEXICO, ARGENTINA & COLOMBIA	SEP 2016	CHF 11 MN	CHF 5 MN: - CHF 4 MN REGULATORY - CHF 1 MN SALES	UNDISCLOSED	BASILEA SELLS PRODUCT(S) AT TRANSFER PRICE
UNIMEDIC	CRESEMBA ZEVTERA	THE NORDICS INCL. SWEDEN, DENMARK, NORWAY & FINLAND	SEP 2016	UNDISCLOSED	--	UNDISCLOSED	BASILEA SELLS PRODUCT(S) AT TRANSFER PRICE
AVIR PHARMA	CRESEMBA ZEVTERA	CANADA	JUN 2017	CHF 1.3 MN	--	UNDISCLOSED	BASILEA SELLS PRODUCT(S) AT TRANSFER PRICE
ADVANZ PHARMA (FORMERLY CORREVIO)	ZEVTERA	MORE THAN 30 COUNTRIES IN EUROPE (EXCL. THE NORDICS)	SEP 2017	CHF 5 MN	--	UNDISCLOSED	BASILEA SELLS PRODUCT(S) AT TRANSFER PRICE
JSC LANCET	ZEVTERA	RUSSIA & EURASIAN ECONOMIC UNION	JUL 2021	UNDISCLOSED	--	UNDISCLOSED	BASILEA SELLS PRODUCT(S) AT TRANSFER PRICE

SOURCE: BASILEA PHARMACEUTICA, VALUATIONLAB

Next to license agreements, Basilea has signed several distribution agreements, where it sells its products at a transfer price, to increase the global reach of Zevtera and Cresemba. In 2015, Hikma became the distributor of Zevtera in the MENA region and extended the agreement to Cresemba in 2016. In 2016, Grupo Biotoscana (acquired by Knight Therapeutics in October 2019) became the distributor of Cresemba and Zevtera in 19 countries in Latin America, including Brazil, Mexico, Argentina, and Colombia, while Unimedic became the distributor for both products in the Nordics, including Sweden, Denmark, Norway, and Finland. In 2017, Avir Pharma became the distributor for Cresemba and Zevtera in Canada, while Correvio (acquired by Advanz Pharma in May 2020) became the distributor of Zevtera in more than 30 countries in Europe (excluding the Nordics). In July 2021, a distribution agreement was announced with JSC Lancet for Zevtera covering the Eurasian Economic Union countries.

Derazantinib rights returned to Merck & Co: The license agreement for the FGFR inhibitor derazantinib (bile duct, bladder, and stomach cancer) was terminated, and the rights will be returned to Merck & Co by the end of 2022. Basilea concluded that a transaction could not be closed at the terms and within the timelines required due to the changing competitive landscape and the evolving clinical data from its open-label trials.

PARG inhibitor program sold to Nodus: In September 2022, Basilea announced the sale of its preclinical PARG (poly(ADP-ribose) glycohydrolase) inhibitor program to Nodus Oncology. Basilea will receive upfront and near-term research milestone payments of CHF 1 mn from Nodus Oncology and is eligible for further payments of up to CHF 241 mn for development, regulatory, and sales milestones in addition to approximately 5% sales royalties.

BAL0891 sold to SillaJen: In September 2022, Basilea also entered into an asset purchase and sub-license agreement with SillaJen Inc. for its novel kinase inhibitor BAL0891. Basilea in-licensed BAL0891 from NTRC, a Dutch precision medicine company, in 2018. Under the asset purchase agreement, Basilea is selling its intellectual property rights generated under the license and collaboration agreement with NTRC, next to sublicensing its rights and obligations to SillaJen. Basilea received upfront and near-term milestone payments of USD 14 mn from SillaJen and is eligible to receive development, regulatory, and sales milestones of up to USD 320 mn and tiered sales royalties starting in the single-digit range going up to double-digits. Basilea remains responsible for making milestone and royalty payments to NTRC.

CLK kinase inhibitor program sold to Redona: In November 2022, Basilea entered into an asset purchase agreement with Redona Therapeutics (formerly Twentyeight-Seven Therapeutics) for its novel preclinical CLK kinase inhibitor program. Basilea will receive an upfront payment of CHF 1 mn and potential near-term milestone payments of CHF 2 mn and is eligible for development, regulatory, and sales milestone payments of up to CHF 351 mn.

III) Cresemba (isavuconazole) pivotal phase III data:

The approval of Cresemba in mold infections was based on two positive phase III trials. The phase III program with Cresemba to investigate its role in treating invasive fungal infections consisted of three phase III trials:

1. **"SECURE"** is a global double-blind randomized phase III trial, designed to evaluate the safety and efficacy of once-daily Cresemba versus Pfizer's twice-daily Vfend (voriconazole) in the primary treatment of invasive fungal disease caused by Aspergillus species or other filamentous fungi: Primary & secondary endpoints met
2. **"VITAL"** an open-label phase III trial of Cresemba in the treatment of aspergillosis patients with pre-existing renal impairment or patients with invasive fungal disease caused by emerging and often fatal molds, yeasts, or dimorphic fungi: Effective in aspergillosis patients with renal impairment & effective in mucormycosis
3. **"ACTIVE"** a phase III trial evaluating the safety and efficacy of intravenously (IV) and orally administered Cresemba versus Merck & Co's IV Cancidas (caspofungin) followed by Pfizer's oral Vfend in the treatment of invasive Candida infections: Primary endpoint missed while secondary endpoints met; Basilea will not seek approval of Cresemba for treating invasive yeast infections

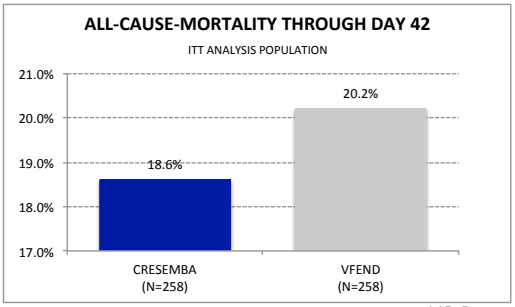
1) "SECURE" – Positive pivotal phase III trial for treating invasive aspergillosis

"SECURE" was a randomized, double-blind, non-inferiority active-controlled trial, which evaluated the safety and efficacy of Cresemba versus Pfizer's Vfend (voriconazole) for primary treatment of invasive fungal disease caused by Aspergillus species or other

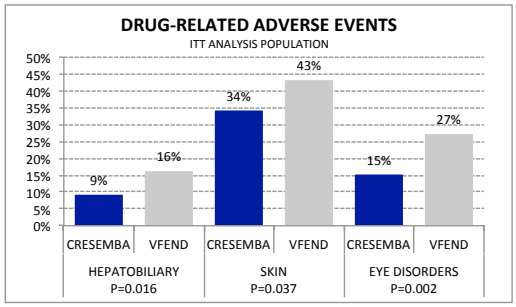
filamentous fungi. Patients randomized to Cresemba treatment started with the IV formulation given every 8 hours for the first 48 hours. From day 3 onwards, patients received IV or oral therapy once daily. Patients randomized to Vfend treatment started with the IV formulation with a loading dose every 12 hours for the first day, followed by a lower IV dose every 12 hours for the following day. Therapy could then be switched to an oral formulation of Vfend twice daily. The protocol-defined maximum treatment duration was 84 days. The mean treatment duration was 47 days for both treatment groups, of which 8 to 9 days were by an intravenous route of administration.

Primary endpoint met: non-inferiority in all-cause-mortality through day 42

The primary endpoint of "all-cause-mortality through day 42" in the overall population (ITT: intent-to-treat) was 18.6% in the Cresemba treatment group and 20.2% in the Vfend treatment group for an adjusted treatment difference of -1.0% with 95% confidence interval



SOURCE: VALUATIONLAB, BASILEA



SOURCE: VALUATIONLAB, BASILEA

of -8.0% to 5.9%. Similar results were seen in patients with proven or probable invasive aspergillosis confirmed by serology, culture, or histology.

Favorable safety profile with fewer drug-related adverse events in several organs

The overall safety profile of Cresemba showed similar rates of mortality and adverse events as with Vfend in the overall ITT population. In patients with invasive aspergillosis, there were significantly fewer drug-related adverse events with Cresemba (42.4%) compared to Vfend (59.8%). As can be seen in the chart above there were statistically fewer treatment-emergent adverse events in several organ classes with Cresemba, including hepatobiliary (liver, gallbladder & bile ducts), skin, and eye disorders.

2) "VITAL" - Open-label trial with Cresemba in invasive mucormycosis

VITAL was an open-label non-comparative trial that evaluated the safety and efficacy of a subset of patients with invasive mucormycosis (a rare mold infection with a high mortality rate and few treatment options). 37 patients had proven or probable mucormycosis. Patients were treated with Cresemba intravenously or via oral administration at the recommended doses. The median treatment duration was 102 days for patients classified as primary treatment, 33 days for refractory patients, and 85 days for patients intolerant to other antifungal treatments.

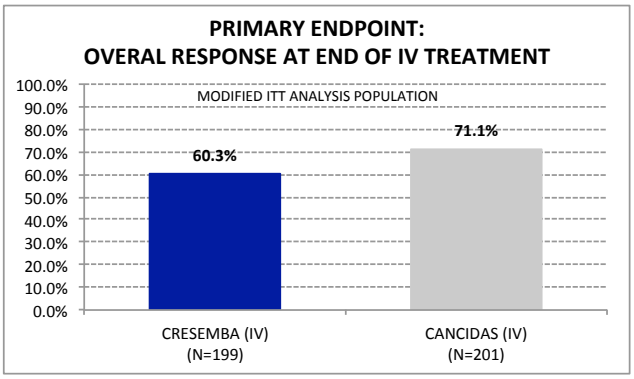
The results provided evidence that Cresemba is effective for the treatment of mucormycosis, in light of the natural history of untreated mucormycosis:

- All-cause mortality through day 42 in renally-impaired patients with invasive aspergillosis (n=20) **for which IV Vfend can only be used with caution**:
  - 15% (vs. 18.6% benchmark in the "SECURE" trial, excluding patients with moderate to severe renal impairment)

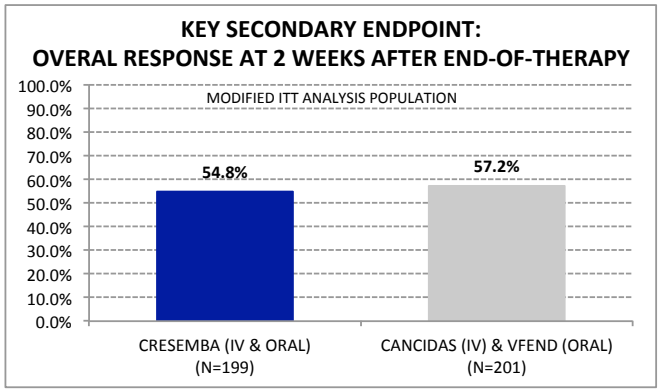
- All-cause mortality through day 42 in patients with confirmed mucormycosis (n=37), **including patients refractory or intolerant to other antifungal therapies**
    - 37.8% (similar to data reported in the literature) NOTE: only amphotericin B is approved for these patients but at the cost of high toxicities

3) "ACTIVE" – Primary endpoint missed – potential for oral step-down not pursued

The randomized double-blind phase III "ACTIVE" trial evaluated the efficacy and safety of intravenously and orally administered Cresemba versus a regimen of Merck & Co's intravenously administered Cancidas (caspofungin) followed by an optional switch to Pfizer's oral Vfend (voriconazole) in adult patients with candidemia and other invasive Candida infections.



SOURCE: VALUATIONLAB, BASILEA



SOURCE: VALUATIONLAB, BASILEA

The topline results, which were announced on July 30th, 2015, showed that "ACTIVE" did not meet the primary objective of demonstrating non-inferiority of Cresemba compared to Cancidas at the end of initial IV therapy, within the pre-specified non-inferiority margin of 15%. At the end of initial IV therapy, Cresemba showed an overall response rate of 60.3%, while Cancidas recorded 71.1%, with the lower bound of the 95%-confidence interval outside the pre-specified non-inferiority margin.

Regarding the overall response rates at two weeks after the end of treatment, these were comparable between the two treatment groups (54.8% with Cresemba (IV & oral step-down therapy) and 57.2% with Cancidas (IV) & optional Vfend oral step-down therapy). Overall response at two weeks after the end of treatment was the key secondary endpoint of the study. In addition, the secondary endpoint of all-cause mortality was comparable on study day 14 and day 56 in both treatment groups. Upon review of topline data, the overall safety profile of Cresemba was similar to the Cancidas/Vfend group and consistent with safety data seen in the previously reported phase III trials. Basilea will not actively pursue Cresemba as oral step-down therapy.

IV) Zevtera (ceftobiprole) pivotal phase III data:

EU/ROW development program for treating serious lung infections

Because of its broad-spectrum activity against lower respiratory tract pathogens, Zevtera was evaluated in two phase III trials in the treatment of CABP (community-acquired bacterial pneumonia) and HABP (hospital-acquired bacterial pneumonia). Both trials formed the basis of the EU approval, and as a result, Zevtera is the first cephalosporin with MRSA coverage approved in the EU as monotherapy for the treatment of both CABP and HABP, excluding VABP (ventilator-associated bacterial pneumonia).

1) CABP phase III trial: This was a randomized, double-blind, comparative study of intravenous Zevtera 3x daily versus intravenous ceftriaxone (generic Rocephin) once daily with or without Pfizer's intravenous Zyvox (linezolid) twice daily in the treatment of patients hospitalized with CABP. Zyvox was allowed for subjects with proven or suspected MRSA or ceftriaxone-resistant S. pneumoniae.

Zevtera demonstrated non-inferiority compared to the ceftriaxone +/- Zyvox regimen with comparable cure rates:

- For the primary endpoint in 469 clinically evaluable (CE) patients, cure rates were 86.6% for Zevtera versus 87.4% for ceftriaxone +/- Zyvox; in the ITT analysis of 638 CABP patients, these cure rates were 76.4% versus 79.3%, respectively.
- For the secondary endpoint of clinical cure in patients with a pneumonia severity index ≥91, the cure rates for the above regimens were 90.2% and 84.5% compared with 85.6% and 88.3% for those with lower scores, respectively.
- In patients with CABP complicated by bacteremia, cure rates were 85.7% versus 85.7%; and with the presence of systemic inflammatory response syndrome 84.6% versus 86.7%, respectively.

2) HABP phase III trial: This was a double-blind, randomized, multicenter study of 781 patients with hospital-acquired bacterial pneumonia (HABP), including 210 with ventilator-associated bacterial pneumonia (VABP). Treatment was intravenous Zevtera 3x daily, or GSK's intravenous Fortaz (ceftazidime) 3x daily plus Pfizer's intravenous Zyvox (linezolid) twice daily. The primary outcome was clinical cure at the test-of-cure visit.

Zevtera proved non-inferiority compared to the Fortaz + Zyvox combination with comparable cure rates and microbiologically eradication rates, except in VABP patients where it was not non-inferior to the comparator. Hence, VABP patients are excluded from Zevtera's EU label. In summary:

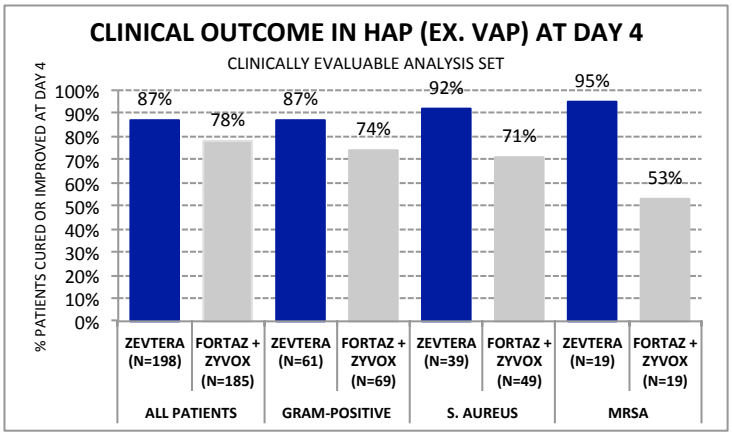
- Overall cure rates for Zevtera vs. Fortaz + Zyvox were 49.9% vs. 52.8% (intent-to-treat (ITT), with a 95% confidence interval (CI) for the difference, -10.0 to 4.1); and 69.3% vs. 71.3% (clinically evaluable (CE), 95% CI, -10.0 to 6.1).
- Cure rates in HABP (excluding VABP) patients were 59.6% vs. 58.8% (ITT, 95% CI, -7.3 to 8.8); and 77.8% vs. 76.2% (CE, 95% CI, -6.9 to 10.0).
- Microbiological eradication rates in HABP (excluding VABP) patients were 62.9% vs. 67.5% (microbiologically evaluable (ME), 95% CI, -16.7 to 7.6).
- Cure rates in VABP patients were 23.1% vs. 36.8% (ITT, 95% CI, -26.0 to -1.5) and 37.7% vs. 55.9% (CE, 95% CI, -36.4 to 0).
- Microbiological eradication rates in VABP patients were 30.4% vs. 50.0% (ME, 95% CI, -38.8 to -0.4).
- A small difference was also seen in clinical cure rates in all patient and ICU (intensive care unit) patients in the CE analysis set at the test-of-cure visit, underlining non-inferior efficacy compared to the standard antibiotic combination.

Treatment-related adverse events were comparable for Zevtera (24.9%) and Fortaz + Zyvox (25.4%). The most common treatment-related side effects (reported by 3% or more patients) included nausea, vomiting, diarrhea, infusion site reactions, hypersensitivity, and taste impairment.

Post-hoc analyses show an early clinical response on day 4

An early clinical response was seen with Zevtera in HABP (excluding VABP) in a post-hoc analysis of the phase III HABP trial. In a clinically evaluable (CE) analysis set, Zevtera showed a marked early clinical response on day 4 compared to the standard Fortaz + Zyvox antibiotic combination in all patients as well as in various subgroups, including patients with Gram-positive infections, S. aureus, and MRSA (the need for Zyvox in the standard antibiotic combination as Fortaz spectrum of activity does not cover MRSA).

Patients treated with Zevtera could potentially be discharged from the hospital earlier with a positive impact on overall treatment costs.



SOURCE: VALUATIONLAB, BASILEA

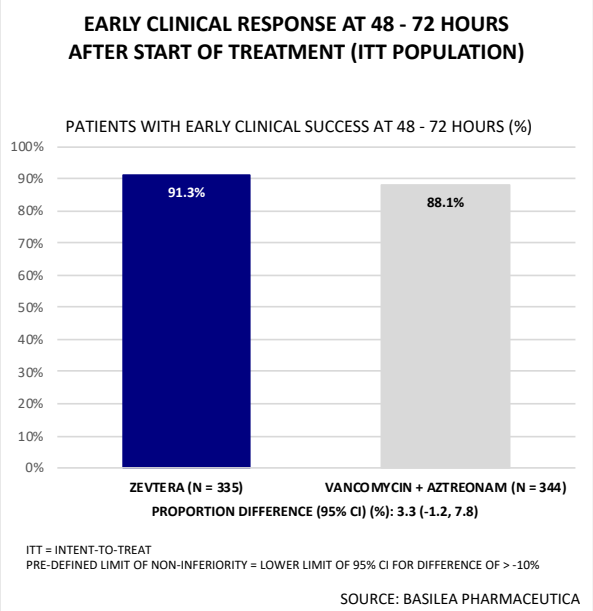
US development program for treating ABSSSI and SAB

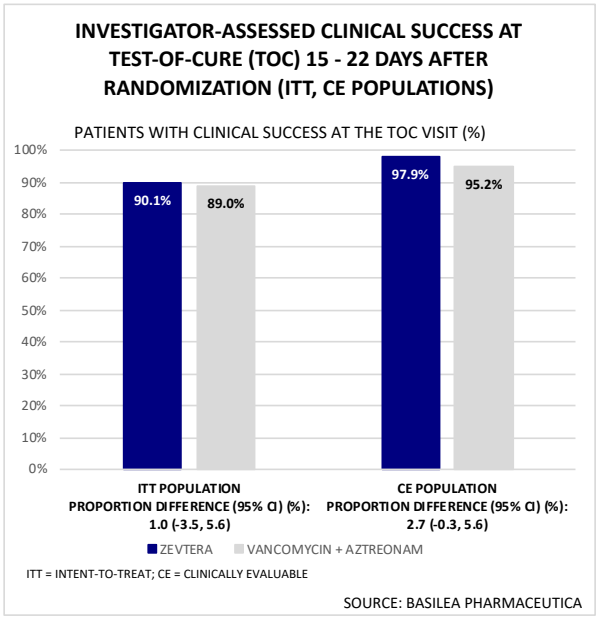
Basilea started the US phase III development of Zevtera in February 2018, with the start of the phase III ABSSSI "TARGET" trial followed by the SAB "ERADICATE" trial in August 2018. US filing requires that both trials be completed.

1) "TARGET" ABSSSI phase III trial: This was a phase III trial of Zevtera in acute bacterial skin and skin structure infections (ABSSSI – severe skin infections) named "TARGET" started in February 2018 and reported positive topline results in August 2019. The global, randomized, double-blind, multicenter trial conducted in more than 30 clinical centers in the US and Europe that enrolled 679 patients. The trial compared Zevtera (500 mg, 3x daily 2-hours infusion) to comparator vancomycin (1,000 mg, 2-hours infusion) or vancomycin (15 mg/kg 2x daily 2-hours infusion) plus aztreonam (1000 mg, 2x daily 30 minutes infusion). Aztreonam for Gram-negative coverage is not needed with Zevtera, which broad spectrum of activity also covers many Gram-negative bacteria.

The primary endpoint was early clinical response (time frame: 48 – 72 hours after start of drug treatment); and the main secondary endpoint was investigator-assessed clinical success at the test of cure visit 15-22 days after randomization.

In the pivotal "TARGET" phase III trial Zevtera was non-inferior to vancomycin plus aztreonam for the treatment of ABSSSI. The key endpoints for the FDA and EMA were both met. Success rates showed a trend in favor of Zevtera and the lower bounds of the 95% confidence intervals were all well within the prespecified non-inferiority margin of 10%. Positive results were consistent in an analysis by region for the US and Europe.





Zevtera met the pre-specified primary endpoint of early clinical response at 48 to 72 hours after the start of trial drug administration in the ITT (intent-to-treat) population. This is the key primary endpoint according to the FDA guidance for the US and includes all randomized patients. To achieve this endpoint, the initial skin lesion size had to decrease by 20% or more from the baseline. Response rates were 91.3% with Zevtera versus 88.1% for vancomycin plus aztreonam.

Zevtera also met the pre-specified secondary endpoints of investigator-assessed clinical success at the TOC (test-of-cure visit) 15 to 22 days after randomization. This is the key endpoint for the EMA in Europe. In the ITT population, clinical success was shown in 90.1% of patients treated with Zevtera versus 89% of patients treated with vancomycin plus aztreonam, and in the clinically evaluable or CE population in 97.9% versus 95.2%, respectively. The CE population is the subset of patients in the ITT population with no major protocol deviations. The CE population was approximately 85% of the ITT population in the trial.

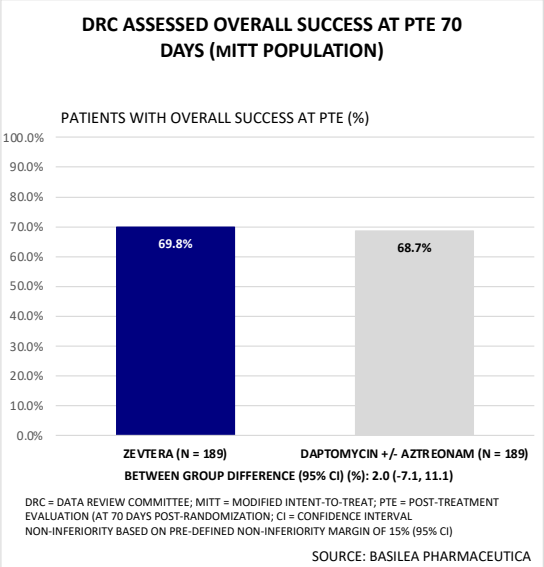
Zevtera was also well-tolerated in the “TARGET” trial. The overall rates of drug-related adverse events were 20% for Zevtera and 18% for vancomycin plus aztreonam and were similar between the two treatment groups. The most common drug-related adverse events in both treatment groups were nausea, diarrhea, and headache, and the safety profile of Zevtera in the “TARGET” trial was consistent with a known safety profile from earlier trials.

2) “ERADICATE” SAB phase III trial: The phase III trial of Zevtera in Staphylococcus aureus bacteremia (SAB - bloodstream infections) named “ERADICATE” started in August 2018. The global, randomized, double-blind, multicenter trial enrolled 390 patients in 60 study centers in 17 countries. The trial compared Zevtera (500 mg, 2-hour infusion) to daptomycin (6 mg/kg, 30-minute infusion – branded Cubicin by Merck & Co) for overall success in the treatment of SAB. Aztreonam (1,000 mg, 30-minute infusion) could be added to daptomycin if the involvement of Gram-negative bacteria was suspected, which is not needed with Zevtera due to its broad spectrum of activity that also covers Gram-negative bacteria. Patient characteristics in the 387 patients included in the modified intent-to-treat (mITT) population were balanced between the Zevtera and daptomycin treatment groups.

The primary endpoint was the overall success rate at the post-treatment evaluation (PTE) visit (time frame: day 70 +/- 5) in the modified intent-to-treat (mITT) population.

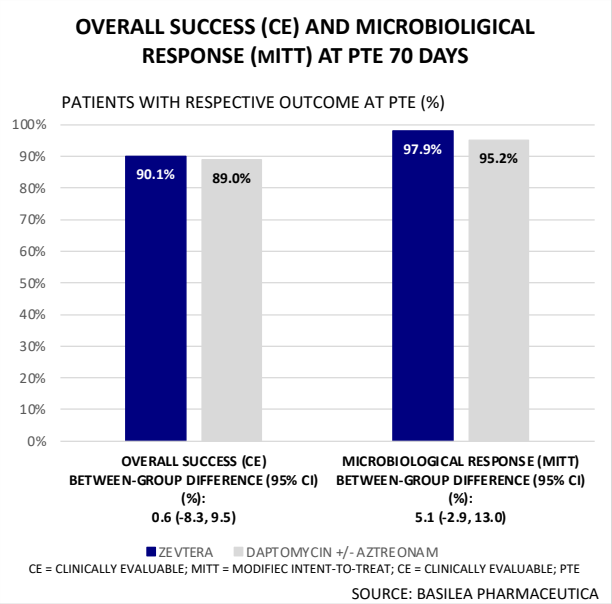
In H1 2020, the FDA approved a protocol amendment to progress the trial to a pre-planned second cohort and extend the maximum treatment duration from four to up to six weeks, which enables to expand enrolment to patients with more difficult-to-treat infections, including those with complications such as osteomyelitis and epidural or cerebral abscess.

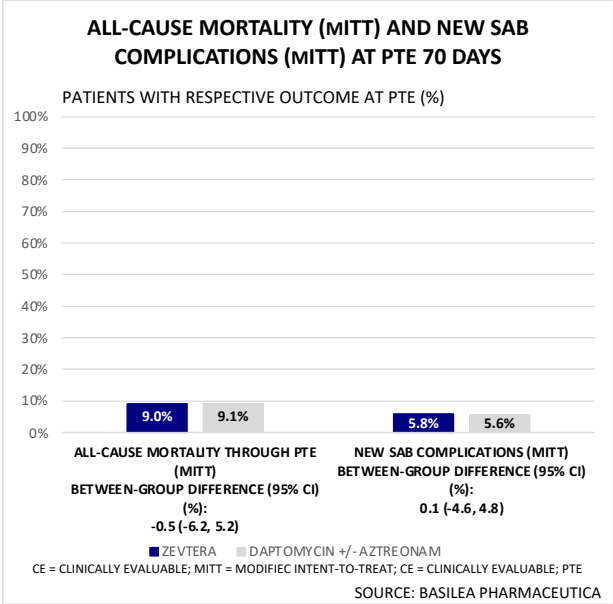
The "ERADICATE" trial was the largest double-blinded randomized phase III trial of a new antibiotic treatment in SAB. Zevtera met the primary endpoint of the overall success rate compared to daptomycin (branded Cubicin by Merck & Co), with or without aztreonam, as well as secondary endpoints while being well-tolerated with a safety profile consistent with previous phase III trials and post-marketing experience.



The overall success rate, assessed by a blinded independent Data Review Committee (DRC), was 69.8% with Zevtera (n=189), compared to 68.7% with daptomycin (n=189), in the mITT population at 70 days post-randomization. The statistically adjusted difference between Zevtera and daptomycin for overall success was 2.0% (95% confidence interval: -7.1% to 11.1%), well within the pre-specified non-inferiority margin of 15%. Results for the primary efficacy outcomes were consistent in key subgroups including patients with MSSA or MRSA bloodstream infections at baseline, and in various categories of underlying conditions such as skin and skin structure infections, abdominal abscesses, chronic dialysis, septic arthritis, osteomyelitis, definite right-sided infective endocarditis and in patients with persistent SAB.

Secondary efficacy outcomes such as the overall success rate in the clinically evaluable population (77.9% in the Zevtera group, 77.8% in the daptomycin group), microbiological eradication (82.0% in the Zevtera group, 77.3% in the daptomycin group), all-cause mortality (9.0% in the Zevtera group, 9.1% in the daptomycin group) and the emergence of new SAB complications (5.8% in the Zevtera group, 5.6% in the daptomycin group) were also similar between the two treatment groups at 70 days post-randomization in the mITT population.





The median time to Staphylococcus aureus bloodstream clearance for MSSA was 3 days with Zevtera and 4 days with daptomycin, and 5 days for MRSA for both Zevtera and daptomycin.

The emergence of resistance under treatment was observed in three patients on daptomycin. No emergence of resistance under treatment was observed with Zevtera.

Both treatments were well tolerated. The overall rate of adverse events was similar between the Zevtera and daptomycin groups. In line with the known safety profile of Zevtera, gastrointestinal disorders were more frequent with Zevtera compared to daptomycin, mainly driven by mild to moderate nausea.

Invasive Fungal Infection Market

The global market for the treatment of invasive fungal infections peaked at USD 3.6 bn in 2015, with a volume-based CAGR 2004-2015 of 17% for newer antifungals, underlining the rise in invasive fungal infections and the need for new effective therapies. Pfizer's Vfend (voriconazole) peaked at approximately USD 900 mn in 2014. Global sales of best-in-class antifungals amounted to USD 2.8 bn (moving annual total (MAT) Q4 2022), according to IQVIA Analytics. Largest-selling antifungals include Pfizer's Vfend (voriconazole) with sales of USD 604 mn (21% market share), followed by Merck & Co's Cancidas (caspofungin) at USD 495 mn (17%) and Noxafil (posaconazole) at USD 472 mn (17%) and Gilead's liposomal formulation of amphotericin B, branded AmBisome at USD 469 mn (17%), Astellas' Mycamine (micafungin) at USD 251 mn (9%), Basilea's Cresemba (isavuconazole) at USD 373 mn (13%), and Pfizer's Eraxis (anidulafungin) at USD 171 mn (6%).

IQVIA Analytics estimates the EU Top-5 countries accounted for 29% of the global invasive antifungal market of new azoles and candins (MAT Q3 2022), followed by the US (22%), ROW (24%), China (21%), and Japan (4%), respectively. The US usually generates a higher proportion of sales with its generally higher treatment prices. This is not the case with invasive antifungals, with limited branded treatment options with relatively high differentiation and few effective generics. This leads to high treatment prices worldwide.

INVASIVE FUNGAL INFECTIONS - KEY FACTS	
MARKET SIZE	USD ~3 BN; ~57% INTRAVENOUS DRUGS (AZOLES, CANDINS, AMPHO B), ~43% ORAL (AZOLES)
PREVALENCE	7.6 MN GLOBALLY; 230-300 MN TOTAL DAYS OF THERAPY (30-39 TREATMENT DAYS/PATIENT)
INCIDENCE	CANDIDIASIS: 10-14 PER 100,000 PEOPLE; ASPERGILLOSIS: 1-2 PER 100,000 (1992 ESTIMATE)
UNDERLYING CAUSE	ACUTE INVASIVE FUNGAL INFECTION OCCURS WHEN THE IMMUNE SYSTEM FAILS TO PREVENT FUNGAL SPORES FROM ENTERING THE BLOODSTREAM. WITHOUT THE BODY MOUNTING AN EFFECTIVE IMMUNE RESPONSE, FUNGAL CELLS ARE FREE TO SPREAD THROUGHOUT THE BODY AND CAN EFFECT MAJOR ORGANS SUCH AS THE HEART, BRAIN, EYES, AND KIDNEYS. INVASIVE FUNGAL INFECTIONS ARE A MAIN CAUSE OF HOSPITALIZATION AND MORTALITY IN IMMUNOCOMPRIMIZED PATIENTS WITH MORTALITY RATES RANGING BETWEEN 25-38% (CANDIDIASIS), 34-58% (ASPERGILLOSIS) AND 40-80% (MUCORMYCOSIS).
SYMPTOMS	INVASIVE ASPERGILLOSIS: - FEVER - CHEST PAIN - COUGH, COUGHING UP BLOOD, SHORTNESS OF BREATH INVASIVE CANDIDIASIS: - FEVER AND CHILLS (THAT DO NOT IMPROVE AFTER ANTIBIOTIC TREATMENT)
DRUG CLASS (KEY BRANDS)	LIPOSOMAL AMPHOTERICIN B: - (AMBISOME) - (FUNGISOME) - (AMPHOTEC) - (ABELCET) (NEXT-GENERATION) TRIAZOLES: - VORICONAZOLE (VFEND) - POSACONAZOLE (NOXAFIL) - ISAVUCONAZOLE (CRESEMBA) (ECHINO)CANDINS: - MICAFUNGIN (MYCAMINE) - CASPOFUNGIN (CANCIDAS) - ANIDULAFUNGIN (ERAXIS)
MAJOR PLAYERS (KEY BRANDS)	- PFIZER (VFEND, ERAXIS, CRESEMBA) - ASTELLAS (MYCAMINE, AMBISOME, CRESEMBA) - MERCK & CO (CANCIDAS, NOXAFIL) - GILEAD (AMBISOME)

SOURCE: VALUATIONLAB, NIH,EMA, WHO, IDSA, CDC, COMPANY REPORTS

Fungal diseases are often caused by fungi that are abundant in the environment, with approximately 1.5 mn different species. They can be divided into mold and yeasts. Most fungi are not dangerous, often colonizing but not causing disease. Only about 300 of these lead to illness. Superficial fungal infections are common, affecting 20-25% of the general population, and are restricted to the skin or mucosal surfaces, such as nail infections. However, in people with a weak immune system, these otherwise harmless fungal infections

can enter the bloodstream and invade critical organs leading to damage or even death. These are the so-called invasive or systemic fungal infections. In particular, patients undergoing treatments that suppress their immune system (immunosuppressants) such as cancer patients, patients with AIDS/HIV, stem cell therapy patients, solid organ recipients, and patients in the ICU (intensive care unit) are at high risk of invasive fungal infections. The aging of the population with a higher incidence of cancer and the increased use of effective immunosuppressants has led to the rise of invasive fungal infections in the hospital.

The two most common invasive fungal infections include:

1. **Aspergillosis:** is caused by a mold called Aspergillus and usually occurs in people with lung diseases or weakened immune systems – mortality rates range between 34-58% (NOTE: in roughly 5-10% of suspected Aspergillus infections, molds from the order of Mucorales can be involved with mortality rates ranging between 40-80%; Cresemba is the only azole indicated for the treatment of mucormycosis)
2. **Candidemia:** is an infection caused by a yeast called Candida, and mostly occurs in people who have recently been admitted to a hospital or have been in contact with other healthcare settings such as nursing homes – mortality rates range between 23-40% (NOTE: Cresemba is not approved for yeast infections)

An increasing rate of invasive fungal infections adding to total treatment costs

These high mortality rates are equal to that of severe sepsis or septic shock. Invasive fungal infections are increasingly observed in non-immunocompromised surgical and critically ill adult patients. An estimated 7.6 mn patients are treated for invasive fungal infections globally per year. Total days of therapy are estimated to amount to 230-300 mn days, or an average of 30-40 days per patient, underling the seriousness of these infections, and the impact on healthcare costs. A US study shows that in patients undergoing solid organ transplants, the occurrence of an invasive fungal infection leads to a 5-fold increase in mortality, an additional 19.2 hospital days, and USD 55,400 in excess costs compared to patients without an invasive fungal infection.

When and how to treat? - Defining patients at risk – Eclectic treatment approach

Early treatment has a profound impact on mortality rates, but reliable diagnostic measures are lacking. For instance, a high proportion of ICU patients become colonized, but only 5% to 30% of them develop an invasive infection. This has led to different treatment strategies including prophylaxis, empirical and pre-emptive treatment, and targeted treatment in response to a definite diagnosis of invasive fungal infection. Defining patients at risk is critical to starting treatment early and with the right treatment choice.

- Patients at risk of invasive aspergillosis comprise patients with AML (acute myelogenous leukemia); patients undergoing stem cell therapy; recipients of solid organs; and other conditions with severe and prolonged immunosuppression.
- Patients at high risk of invasive candidiasis are less well defined. Risk factors are diverse and include hematological malignancy, neutropenia, age < 1 month or > 65 years, and recent abdominal surgery.

The complexity of the clinical problem leads to an eclectic treatment approach. Increasing treatment resistance, including fluconazole and voriconazole resistance, complicates matters further. So the choice of which drug to use should depend on local epidemiology and the above-mentioned patient risk factors with a preference to start therapy with an agent that has a broad spectrum of activity and good tolerability and safety profile.

Hospital Antibiotic Market (Anti-MRSA)

According to Grand View Research, the estimated USD 10+ bn hospital-acquired infections (HAIs) market is set for dynamic change.

On the positive side, market growth will be enhanced by:

1) The prevalence of hospital-acquired infections (HAIs) in intensive care units (ICUs) is increasing globally. Adopting proper infection control measures and reducing the incidence of infection in hospitals, especially in ICUs, has become a necessity since the COVID-19 pandemic has burdened the healthcare sector globally. Patients in intensive care units are twice as likely to get HAIs as those in general wards.
2) A bustle of government initiatives across the globe to incentivize anti-infective research to fight rising bacterial resistance, such as the US GAIN Act in 2012, which provides for priority review and 5 years of additional market exclusivity on approval.

On the negative side, several of the largest-selling hospital antibiotics have lost patent protection, including Pfizer's Zyvox and Merck & Co's Cubicin (daptomycin).

A sub-segment is the anti-MRSA hospital antibiotic market, with global sales of USD 2.6 bn (December 2022, IQVIA Analytics). The US is clearly the most important country for commercialization, with approximately 46% of global sales generated in the US, ~18% in the EU-5, ~15% in China, ~5% in Japan, and ~17% in the ROW. For individual MRSA antibiotics, their value share may reach up to 90%, as seen for Cubicin before the patent loss or for Allergan/Pfizer's Teflaro (ceftaroline).

HOSPITAL BACTERIAL INFECTIONS - KEY FACTS	
MARKET SIZE	USD 2.7 BN ANTI-MRSA HOSPITAL ANTIBIOTICS (MARKET SHARE: US ~46%; EU-5 ~18%; CHINA ~15%)
PREVALENCE	APPROXIMATELY 25 MN PATIENTS PER YEAR IN US, EU-5 AND JAPAN
INCIDENCE	9.2 OUT OF 100 HOSPITAL PATIENTS; 20.6% OF INTENSIVE CARE UNIT PATIENTS
UNDERLYING CAUSE	NOSOCOMIAL OR HOSPITAL INFECTIONS ARE INFECTIONS THAT OCCUR TO PATIENTS AFTER HOSPITAL ADMISSION (E.G. PNEUMONIA, URINARY TRACT, SURGICAL SITE, BLOODSTREAM INFECTIONS) OR ARE SERIOUS INFECTIONS THAT LEAD TO HOSPITALIZATION (E.G. MRSA SKIN AND LUNG INFECTIONS). THESE INFECTIONS ARE CAUSED BY BACTERIA THAT EASILY SPREAD THROUGH THE BODY. MANY HOSPITAL PATIENTS HAVE COMPROMISED IMMUNE SYSTEMS AND ARE LESS ABLE TO FIGHT OFF INFECTIONS. ROUGHLY 40% OF HOSPITAL INFECTIONS ARE CAUSED BY POOR HAND HYGIENE. INTERACTION WITH OTHER PATIENTS AND CAREGIVERS IS ALSO A CAUSE. HOSPITAL PATIENTS STAY ON AVERAGE 2.5 TIMES LONGER IN HOSPITAL THAN PATIENTS WITHOUT INFECTION. EARLY DETECTION AND TREATMENT WITH THE RIGHT ANTIBIOTIC ARE VITAL TO REDUCE MORBIDITY AND MORTALITY. RESISTANCE TO CURRENTLY USED ANTIBIOTICS IS A MAJOR THREAT.
SYMPTOMS	SYMPTOMS VARY BY TYPE AND LOCATION. MANY FORMS OF HOSPITAL INFECTIONS CAN BE DIAGNOSED THROUGH SITE. BLOOD AND URINE CULTURE TESTS CAN CONFIRM THE INFECTION. - INFLAMMATION - FEVER - ABSCESSES - PAIN AND IRRITATION AT INFECTION SITE
DRUG CLASS (KEY BRANDS)	TARGETED LIST OF ANTIBIOTICS THAT ADDRESS SERIOUS HOSPITAL LUNG INFECTIONS: GLYCOPEPTIDES: - VANCOMYCIN (GENERIC) - TELAVANCIN (VIBATIV) - TEICOPLANIN (TARGOCID) LIPOPEPTIDES: - DAPTOMYCIN (CUBICIN) OXAZOLIDINONES: - LINEZOLID (ZYVOX) - TEDIZOLID (SIVEXTRO) GLYCYLCYCLINES: - TIGECYCLINE (TYGACIL) CEPHALOSPORINS (5TH GENERATION): - CEFTAROLINE (TEFLARO) - CEFTOBIPROLE (ZEVTERA/MABELIO) ANTIBIOTIC COMBINATIONS: - PIPERACILLIN/TAZOBACTAM (ZOSYN)
MAJOR PLAYERS (KEY BRANDS)	- PFIZER (ZYVOX, TYGACIL, ZOSYN, SYNERCID) - MERCK & CO (CUBICIN, SIVEXTRO) - THERAVANCE (VIBATIV) - SANOFI (TARGOCID) - ALLERGAN (TEFLARO) - BASILEA (ZEVTERA/MABELIO)

SOURCE: VALUATIONLAB, NIH,EMA, WHO, IDSA, CDC, COMPANY REPORTS

The human body is home to billions of bacteria (small microorganisms) that can be found on skin surfaces in the intestinal tract, the mouth, nose, and other body openings. Only a small amount of the billions of bacteria in our body cause disease and infection, which can usually be treated with the current selection of antibiotics. However, once bacteria become resistant to some or all major antibiotic classes, they become dangerous because they reproduce rapidly. Without any new treatment options, people who are exposed to them, in particular those with a weak immune system, will often die.

Bacteria can be classified into two groups, Gram-positive or Gram-negative, based on the composition of their cell wall, with a technique called Gram staining, named after Hans Christian Gram, who developed this technique.

Antibiotics are developed to selectively kill (bactericidal) or stop the growth of (bacteriostatic) the desired bacteria, but not the cells in a human body. Each type of antibiotic affects bacteria in different ways and is focused on a number of cellular processes that bacteria rely on for growth and survival, including:

- **Cell wall growth:** Crippling production of the bacterial cell wall that protects the cell from the external environment. Penicillin and vancomycin interact with this mechanism.
- **Protein synthesis:** Interfering with protein synthesis by binding to the machinery that builds proteins, amino acid by amino acid. Tetracyclines, macrolides, aminoglycosides, and oxazolidinones interact here.
- **Metabolic processes:** Wreaking havoc with metabolic processes, such as the synthesis of folic acid that bacteria need to thrive. Trimethoprims and sulphonamides interact with this mechanism.
- **Synthesis of DNA and RNA:** By blocking the synthesis of DNA and RNA, one blocks the reproduction of resistant strains. Quinolones and rifamycins interact here.

Inappropriate antibiotic use and hospitalization induce drug-resistant bacteria

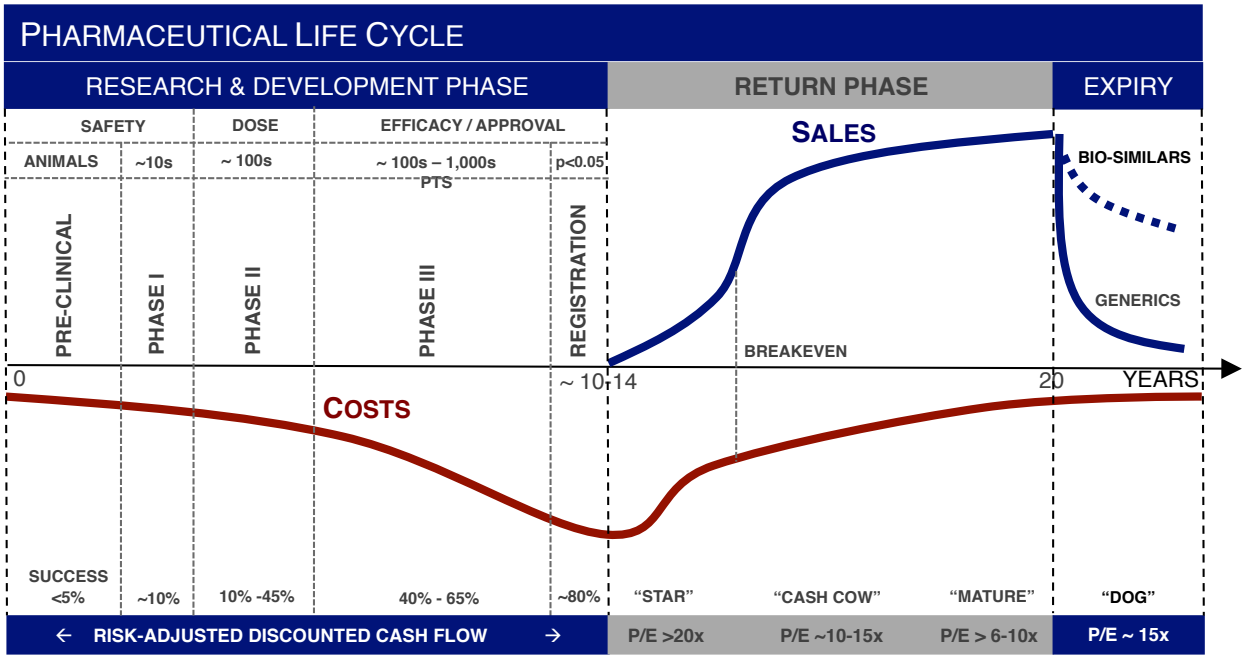
Bacteria are single-celled organisms that have a small number of genes. Therefore, even a single random gene mutation can greatly affect their ability to transmit disease. And because most microbes reproduce by dividing every few hours, bacteria can evolve rapidly. A mutation that helps a microbe survive exposure to an antibiotic drug will quickly become dominant throughout the bacterial population. The advantage bacteria derive from their natural adaptability has increased because of the widespread and often inappropriate use of antibiotics. When a patient does not take the antibiotic according to the prescription over the required treatment, drug-resistant bacteria not killed in the first days of treatment can spread. Hospitals provide a fertile environment for drug-resistant bacteria as close contact among sick patients and extensive use of antibiotics prompt bacteria to develop resistance.

Resistant Gram-positive bacteria (e.g., MRSA) are a major cause of hospital infections

Drug-resistant pathogens pose an increasing threat, particularly in hospitals and other treatment settings. Nearly 2 mn patients in the US acquire an infection in a hospital each year. More than 70% of the bacteria that cause hospital-acquired infections are resistant to at least one of the first-line antibiotics used. Of those patients, about 90,000 die each year. Gram-positive bacteria are a major cause of hospital-acquired and community-acquired infections. MRSA (methicillin-resistant Staphylococcus aureus) bacterial infections are sharply on the rise, both in the hospital and community. Hospital-acquired MRSA is prevalent in Japan, the US, Italy, and Spain, is often multi-drug resistant, and accounts for up to 20-40% of all hospital-acquired pneumonia, where treatment failure rates are high, caused by the inadequate duration of therapy.

Pharmaceutical Life Cycle

To determine the value of a prescription (bio)pharmaceutical compound, it is critical to understand its life cycle. Fortunately, all compounds follow the same life cycle. The clock starts ticking after the compound is patented, providing 20 years of protection from generic competition. Market exclusivities can extend this protection period. Additional protection is provided by orphan drug status (10 years in the EU, 7 years in the US). The average Research & Development Phase takes 8-14 years, leading to an effective Return Phase of 6-12 years. The Development Phase has 3 distinct Phases, focused on safety (Phase I), dose (Phase II), and efficacy/clinical benefit (Phase III). The compound is filed for registration/approval at the FDA (US) or EMA (EU). The Return Phase is characterized by a star, cash cow, and mature phase. After patent expiry (or loss of market exclusivity) generic manufacturers may copycat the branded prescription drug, at significantly lower costs, leading to a sales and earnings implosion of the branded drug.



SOURCE: VALUATIONLAB

Success Probabilities & Royalties

In our risk-adjusted NPV calculations, we use standardized success probabilities based on historical clinical success rates. The success rate increases as the project progresses through development. Sales and earnings forecasts are based on the clinical and competitive profile of the compound. The more advanced the compound is, the more accurate the forecasts become as the target market can be defined. We conservatively exclude projects that lack Phase II proof-of-concept data in our valuations.

SUCCESS PROBABILITIES & ROYALTIES

DEVELOPMENT STAGE	AIM	WHAT / WHO	SUCCESS PROBABILITY (%)	COSTS (USD MN)	ROYALTIES (%)
PRE-CLINICAL	SAFETY & PHARMACOLOGY DATA	LAB TESTS / ANIMALS - NO HUMANS!	< 5	3	
PHASE I	SCREENING FOR SAFETY	HEALTHY VOLUNTEERS (10'S)	5-15	3	< 5
PHASE IIA	PROOF-OF-CONCEPT	PATIENTS WITH DISEASE (10'S)	10-20		
PHASE II	ESTABLISH THE TESTING PROTOCOL	PATIENTS WITH DISEASE (100'S)	15-35	5	5-15
PHASE IIB	OPTIMAL DOSAGE	PATIENTS WITH DISEASE (100'S)	20-45	5-10	
PHASE III	EVALUATE OVERALL BENEFIT/RISK	PATIENTS WITH DISEASE (1,000'S)	40-65	> 20-1,000	10-25
REGULATORY FILING	DETERMINE PHYSICIAN LABELING	CLINICAL BENEFIT ASSESSMENT	80-90		
APPROVAL	MARKETING AUTHORIZATION	PHYSICIANS FREE TO PRESCRIBE	100		15-30

SOURCE: VALUATIONLAB, TUFTS, FDA, EMA, CLINICALTRIALS.GOV

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Our financial analyses are based on the "Directives on the Independence of Financial Research" issued by the Swiss Bankers Association in January 2008.

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Risk Qualification

Speculative	less than 1-year cash and breakeven beyond 1 year
High Risk	profitable within 2 years and 1 approved product/key indication (patent expiry > 5 years)
Medium Risk	profitable and/or sales from at least 2 marketed products/key indications (patent expiry > 5 years)
Low Risk	profitable and sales from >2 marketed products/key indications (patent expiry > 5 years)

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