VALUATIONLAB
FINANCIAL ANALYSIS

BASILEA PHARMACEUTICA

FOCUS AREA: INVASIVE BACTERIAL AND FUNGAL INFECTIONS AND NON-RESPONSIVE OR TREATMENT-RESISTANT CANCER

KEY DATA			SIX: BSLN
MARKET CAPITALIZATION (CHF MN)	547	**SHARE PRICE ON SEPTEMBER 13, 2019**	46
ENTERPRISE VALUE (CHF MN)	347	**RISK-ADJUSTED NPV PER SHARE** (CHF)	126
GROSS CASH (30 JUNE 2019) (CHF MN)	178	**UPSIDE/DOWNSIDE** (%)	174%
MONTHLY OPERATING EXPENSE (CHF MN)	13.3	**RISK PROFILE**	MEDIUM
CASH LIFE (YEAR)	>2021	**SUCCESS PROBABILITY LEAD PIPELINE PROJECT**	72.5%
BREAK-EVEN (YEAR)	2020/2021	**EMPLOYEES**	220
FOUNDED (YEAR)	2000	**LISTED** (YEAR)	2004
KEY PRODUCTS:	**STATUS**	**MAJOR SHAREHOLDERS:**	**(%)**
- ZEVTERA (BACTERIAL LUNG INFECTIONS)	LAUNCHED (EU)	- RBC INVESTOR + TREASURY SERVICES	5.8
- CRESEMBA (INVASIVE FUNGAL INFECTIONS)	LAUNCHED (US & EU)	- CI INVESTMENTS / BLACK CREEK FUNDS	5.1
- DERAZANTINIB (ICCA*/UROTHELIAL CANCER)	PHASE II	- CREDIT SUISSE	< 3
- BAL101553 (SOLID TUMORS)	PHASE I/II	- EXECUTIVE MANAGEMENT	0.0
- BAL3833 (SOLID TUMORS)	PHASE I	**- FREE FLOAT**	**100**
		- AVERAGE DAILY VOLUME (30-DAY)	95'374
UPCOMING CATALYSTS:	**DATE**	**ANALYST(S):**	BOB POOLER
- BAL101553: RESULTS PHASE IIA BRAIN/OVARIAN CANCER TRIAL	END 2019		BP@VALUATIONLAB.COM
- DERAZANTINIB: INTERIM DATA PHASE I/II UROTHELIAL TRIAL	H2 2020		+41 79 652 67 68
- DERAZANTINIB: RESULTS REGISTRATIONAL ICCA* TRIAL	H2 2020		

* ICCA - INTRAHEPATIC CHOLANGIOCARCINOMA (FORM OF BILE DUCT CANCER); ** ABSSSI - ACUTE BACTERIAL SKIN & SKIN STRUCTURE INFECTIONS

ESTIMATES AS OF 16 SEPTEMBER, 2019

SOURCE: VALUATIONLAB ESTIMATES, BASILEA PHARMACEUTICA

On TARGET

Zevtera effective in skin infections, Cresemba surges

Basilea develops prescription pharmaceuticals that address the clinical challenge of the increasing resistance and non-response to current treatments in the areas of bacterial and fungal infections and cancer, which are often associated with high mortality rates. Two of Basilea's anti-infectives have been launched: 1) Zevtera (lung infections) was launched in Europe in 2015 with Correvio responsible for commercialization since 2017; and 2) Cresemba (invasive mold infections) was 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 now provide positive cash flows in launched markets thanks to the recent partnering and distribution agreements. Substantial upside could come from Basilea's investments in Zevtera US development (positive phase III "TARGET" trial results in ABSSSI reported in August 2019) and its emerging clinical oncology pipeline. With CHF 178 mn gross cash (30 June 2019), and up to USD 128 mn funding from the US Biomedical Advanced Research and Development Authority (BARDA), funds should be sufficient to approach profitability in 2020/2021, develop Zevtera and commercialize in the US with a partner, and develop oncology drugs derazantinib, BAL101553 and BAL3833, up to next value inflection points. Our sum-of-parts risk-adjusted NPV (rNPV) amounts to CHF 126/share with a Medium Risk, risk profile.

Key catalysts:

1) **Results phase IIa POC trial of BAL101553 in brain & ovarian cancer (end 2019):** Our rNPV increases by CHF 8/share with a 15% success probability on positive POC (proof-of-concept). Moreover, these results could trigger a lucrative partnering deal.
2) **Interim data derazantinib/Tecentriq POC trial in urothelial cancer (H2 2020):** interim data biomarker-driven multi-cohort phase I/II POC trial of derazantinib with or without Roche's PD-L1 checkpoint inhibitor Tecentriq (atezolizumab) in patients with advanced urothelial cancer.
3) **Results registrational trial of derazantinib in iCCA (H2 2020):** on positive results in patients with iCCA (intrahepatic cholangiocarcinoma) our rNPV increases by CHF 1/share with an 80% (filing) success rate.

Strategy & Cash Position

Focus on drugs for bacterial & fungal infections and treatment-resistant cancer
Basilea is a Swiss biopharmaceutical company dedicated to discovering, developing and commercializing hospital prescription drugs to treat bacterial and fungal infections, and cancer, targeting the challenge of rising resistance and non-response to current treatments. The company is based in Basel, Switzerland. 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. Basilea was listed on the SIX Swiss Stock Exchange (ticker: BSLN) in March 2004. Basilea has approximately 220 employees. Its integrated research covers broad areas of expertise to combat drug resistance, such as microbiology, biochemistry, cancer biology, pharmacology, analytics and medicinal chemistry among others.

Attractive mix of marketed products and an emerging oncology pipeline
Basilea is one of the few biopharmaceutical companies that has successfully developed and brought its own clinical development projects to market. The company's current product offering includes two marketed products and four clinical pipeline projects. Revenue of its two marketed products are being reinvested, together with external funding such as from the Biomedical Advanced Research and Development Authority (BARDA), to develop its pipeline projects up to next inflection points to maximize their value. With sufficient cash to implement its current development plans, Basilea is expected to turn profitable in 2020/2021.

Marketed products (revenue generators):

1) **Cresemba (peak sales CHF 800+ mn):** profitable, marketed for fungal infections by Astellas in the US (launched), by Pfizer in Europe (excl. the Nordics) and China & Asia Pacific Region (launched in major EU countries, not yet launched in China & Asian Pacific region); and various distribution partners globally (approved in Peru and Jordan); Japanese approval expected in 2022 by development & commercialization partner Asahi Kasei; marketed in 33 countries globally, which is expected to reach 40 by end 2019 and 60 by end 2021
2) **Zevtera (peak sales CHF 100+ mn):** profitable in 2019E, marketed for severe lung infections by various distribution partners such as Correvio (formerly Cardiome) in Europe, Unimedic in the Nordics, Grupo Biotoscana in Latin America, Hikma in the MENA region, and development & commercialization partner CR Gosun in China, Hong Kong, Macao (approval in 3 to 4 years); currently launched in 17 countries globally

Clinical pipeline (cash burn):

1) **Zevtera (peak sales CHF 300+ mn):** in 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), positive top line results "TARGET" results were reported in August 2019, top line

results of "ERADICATE" are expected in H2 2021; BARDA covers ~70% of development costs; potential to license to a US commercialization partner; US represents most important region for branded anti-MRSA hospital antibiotics

2) **Derazantinib (peak sales CHF 100+ mn):** global rights (excl. Greater China) acquired from ArQule in April 2018; in a registrational phase II trial in centers in the US, Italy and Canada for its first, fast-to-market, orphan indication iCCA (intrahepatic cholangiocarcinoma), a form of bile duct cancer; in August 2019 a phase I/II POC trial started to investigate the use of derazantinib alone or in combination with Roche's Tecentriq (atezolizumab) in patients with advanced urothelial cancer (not yet in our forecasts), Roche provides Tecentriq for free; Basilea continues to explore pre-clinically the potential utility in other major cancer types
3) **BAL101553 (peak sales CHF 500+ mn):** not yet included in our forecasts due to lack of proof-of-concept (POC); in phase I/II development in glioblastoma (brain cancer) and ovarian cancer; the Adult Brain Tumor Consortium started an open-label phase I trial in newly diagnosed glioblastoma patients early 2018 underlining BAL101553's potential and the lack of effective treatments
4) **BAL3833 (peak sales CHF ~500 mn):** not yet included in our forecasts due to lack of POC; global rights acquired from UK consortium in April 2015; partner Institute of Cancer Research completed phase I (dose escalation) trial in cancer patients; maximum tolerated dose not defined; pre-clinical reformulation activities ongoing

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 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 every year from hospital-acquired bacterial infections with many resistant to current antibiotics, and the number is on the rise. 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. Basilea's hospital antibiotic Zevtera is targeting a multibillion-dollar market opportunity, where an increasing amount of bacterial infections no longer respond to current antibiotics.

Invasive fungal infections have increased worldwide and represent a threat for immuno-compromised 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 hospital antifungal Cresemba targets a USD 3.6 bn market opportunity.

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
- **GAIN** (Generating Antibiotic Incentives Now) Act of 2012: provides QIDP (Qualified Infectious Disease Product) status with priority review and 5 years additional US market exclusivity for approved antibiotics

- **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
- **DISARM** (Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms) Act (introduced 2014, under legislation): allows a value-based higher reimbursement for hospital antibiotics
- **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 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 individual prescription.
- **UK government plan:** Drug-resistant "superbugs" are as big a threat as climate change. By 2040, the UK aims to control and contain antimicrobial resistance (bacteria, viruses, parasites and other infections) and reduce the use of antibiotics in humans by 15% over the next five years. NICE and the NHS will trial a new payment model where drugs will be based on how valuable they are to the NHS instead of by the quantity of drugs sold likely proposing a payment subscription.

Cresemba and Zevtera partnering & distribution deals cover over 100 countries

In the past few years, Basilea has aggressively expanded the global reach of its two anti-infectives Cresemba and Zevtera through extensive partnering and distribution agreements, now covering more than 100 countries with approximately USD 245 mn of upfront and milestone payments received, and up to USD 1.1 bn in potential milestones remaining, next to royalties on product sales. The only sizeable remaining market remaining open for partnerships is for Zevtera in the US expected on FDA approval of Zevtera in ABSSSI and SAB in 2022. The US typically accounts for approximately 70-90% of sales for branded hospital antibiotics and is therefore a critical market for Zevtera

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 57 MN: - CHF 42 MN REGULATORY - CHF 15 MN SALES	CHF 275 MN	TIERED MID-TEENS TO MID-TWENTIES
ASAHI KASEI PHARMA	CRESEMBA	JAPAN	SEP 2016	CHF 7 MN	--	CHF 60 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 5 MN: - USD 5 MN SALES	USD 645 MN	MID-TEEN
CR GOSUN	ZEVTERA	CHINA, HONG KONG, MACAO	SEP 2017	CHF 3 MN	--	CHF 145 MN	DOUBLE-DIGIT TIERED

DISTRIBUTION PARTNERS	PRODUCT(S)	COUNTRIES COVERED	SIGNING DATE	UPFRONT PAYMENT	MILESTONES (RECEIVED)	MILESTONES (OUTSTANDING)	PRICING
HIKMA	ZEVTERA CRESEMBA	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
GRUPO BIOTOSCANA (GBT)	CRESEMBA ZEVTERA	19 COUNTRIES IN LATIN AMERICA INCL. BRAZIL, MEXICO, ARGENTINA & COLOMBIA	SEP 2016	CHF 11 MN	CHF 4 MN: - CHF 2 MN REGULATORY - CHF 2 MN 1ST 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
CORREVIO (FORMERLY CARDIOME)	ZEVTERA	MORE THAN 30 COUNTRIES IN EUROPE (EXCL. THE NORDICS)	SEP 2017	CHF 5 MN	--	UNDISCLOSED	BASILEA SELLS PRODUCT(S) AT TRANSFER PRICE

SOURCE: BASILEA, VALUATIONLAB

In 2017, Basilea signed a partnering agreement with Pfizer for Cresemba in Europe (excluding the Nordics), Russia, Turkey and Israel, and a distribution agreement with Correvio (formerly Cardiome) for Zevtera in more than 30 countries in Europe, effectively replacing the costly dedicated sales force provided by Quintiles in core Europe. As a result, Basilea's Cresemba franchise is now highly profitable (in particular thanks to the strong US uptake by partner Astellas) based on our detailed product forecasts, while Zevtera in severe lung infections could become a profitable franchise as early as in 2019.

Product sales boosted by excellent uptake of Cresemba in the US and Europe

Product revenues from Cresemba and Zevtera (lung infections) are now a mix of product sales (at distributor transfer prices), deferred upfront milestone payments, regulatory and sales milestones, and royalties on sales. For FY 2019, Basilea guides Cresemba and Zevtera product revenues to range between CHF 105-110 mn up 28% to 34% from CHF 82 mn in FY 2018, largely boosted by the excellent uptake of Cresemba in the US (by Astellas) and Europe (by Pfizer).

US development of Zevtera provides a substantial return on investment at low risk

In 2018, Basilea started two-cross supportive phase III trials in severe skin infections ("TARGET" trial) and bacteremia or bloodstream infections ("ERADICATE" trial) under Special Protocol Assessment (SPA) to gain US approval. Qualified Infectious Disease Product (QIDP) status effectively provides 10 years of market exclusivity in the US, while a USD 118 mn contract with the US Biomedical Advanced Research and Development Authority (BARDA) covers approximately 70% of the development costs. The anti-MRSA hospital antibiotics market is valued at USD 3.1 bn with the US being the most important region representing up to 90% of the global market for certain brands, for instance in the case of Merck & Co's Cubicin (daptomycin) before its patent expired. Therefore, we believe US development of Zevtera provides a substantial return on investment for Basilea at a relatively low risk. Specific historical success probabilities for antibiotics in phase III development typically range around 80%. We conservatively assume a 72.5% blended success rate for the US clinical development of Zevtera, the average of a general 65% (phase III) success rate for the "ERADICATE" pivotal trial in SAB and an 80% (filing) success rate for the positive "TARGET" pivotal trial in skin infections. Both cross-supportive pivotal trials are needed for US filing and approval.

Cancer therapies complement Basilea's hospital-focused business

Although chemotherapy has made great strides in treating cancer, non-response and drug resistance remains the major cause of death of cancer patients, where initial treatment often leaves residual disease from which the tumor regrows. Addressing resistance to cancer therapies is an important element in Basilea's strategy to create a sustainable hospital-focused business and complements the company's anti-infective focus. Many cancer treatments often suppress a patient's immune system making them more susceptible to bacterial and fungal infections. Moreover, Basilea's expertise in small molecules and the understanding of the underlying biology that induces drug resistance adds to Basilea's focus on novel cancer treatments, which do not or no longer respond to current treatment options.

Recently licensed derazantinib complements Basilea's oncology portfolio

In April 2018, Basilea expanded its early stage oncology pipeline consisting of BAL101553 (e.g. brain and ovarian cancer) and BAL3833 (solid tumors), with derazantinib. Global rights (excluding China, Hong Kong, Macau and Taiwan) were acquired from ArQule. Derazantinib

is an excellent match for Basilea's existing oncology portfolio. It is a targeted therapy building on a solid biomarker approach in an area where patients currently have limited treatment options. The compound is in late stage registrational phase II development for intrahepatic cholangiocarcinoma (form of bile duct cancer), an orphan disease with granted orphan drug designation in the EU and US. Derazantinib is an oral, small molecule, panFGFR (fibroblast growth factor receptor) inhibitor that targets various cancers including intrahepatic cholangiocarcinoma, bladder, breast, gastric and lung cancer where FGFR alterations exist with a frequency in a range of 5-30%.
In January 2019, Basilea announced a clinical supply agreement with Roche to explore the use of derazantinib alone or in combination with their PD-L1 checkpoint inhibitor Tecentriq in patients with advanced urothelial cancer. In August 2019, a POC trial was started where Roche will provide Tecentriq for free.

Key priorities include Cresemba and Zevtera and its emerging oncology pipeline
In 2019 Basilea will focus on:

1) Continue growing revenues from Cresemba and Zevtera together with its partners including increasing contributions from markets outside the US and Europe
2) Progressing the Zevtera US development program by completing the bacteremia "ERADICATE" pivotal trial with results due in H2 2021, following the first positive phase III cross-supportive "TARGET" trial with Zevtera in severe skin infections announced in August 2019 under BARDA contract
3) For derazantinib, complete enrollment of the of the registrational phase II trial in iCCA and in the recently started POC trial in urothelial cancer with or without Tecentriq
4) Expand clinical programs in oncology up to new value infection points
5) Strengthen anti-infectives and oncology pipeline through internal and external innovation (e.g. license agreement in preclinical research program in potentially first-in-class selective kinase inhibitor announced at H1 2018 results)

H1 2019 results and FY 2019 guidance boosted largely by strong Cresemba sales
In H1 2019, total revenue increased by 5.5% to CHF 63.2 mn. Product revenue and contract revenue was up 13.9% to CHF 53.1 mn boosted by strong product revenues from Cresemba and Zevtera, up 91% to CHF 52.9 mn. This offset the impact from the completion of the non-cash revenue recognition related to Toctino in H1 2018 (CHF 18.8 mn). The operating loss declined by 35% to CHF 13.2 mn. Combined cash and short-term investments amounted to CHF 177.9 mn (30 June 2019). For FY 2019 Basilea guides for: Total revenue of CHF 128-133 mn (reflecting lower than expected BARDA revenue based on lower R&D expenses related to the Zevtera phase III program, and the completion of revenue recognition of Toctino that amounted to CHF 23.9 mn in FY 2018); product revenue from Cresemba and Zevtera of CHF 105-110 mn; operating expenses to remain at approximately the same level as in 2018; resulting in an operating loss of CHF 22-27 mn. Net cash used by operating activities is expected to range between CHF 60-65 mn.

CHF 930 mn raised since inception

Since Basilea was spun-off from Roche in 2000, the company has raised CHF 930 mn. 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	331
CONVERTIBLE BONDS	200
TOTAL RAISED	**930**

SOURCE: VALUATIONLAB ESTIMATES, BASILEA PHARMACEUTICA

The cash was used primarily related to the company's operating activities, in particular the research and development programs, as well as for the buildup of the commercialization organization. Basilea repaid capital of CHF 48 mn (CHF 5 per share) to shareholders in June 2013. Importantly, Basilea succeeded to fully develop three products up to commercialization, including Toctino, launched in 2009; Zevtera, launched in 2014; and Cresemba, launched in 2015. Several early stage discovery projects progressed to the clinic, and an early stage panRAF inhibitor was in-licensed in 2015.

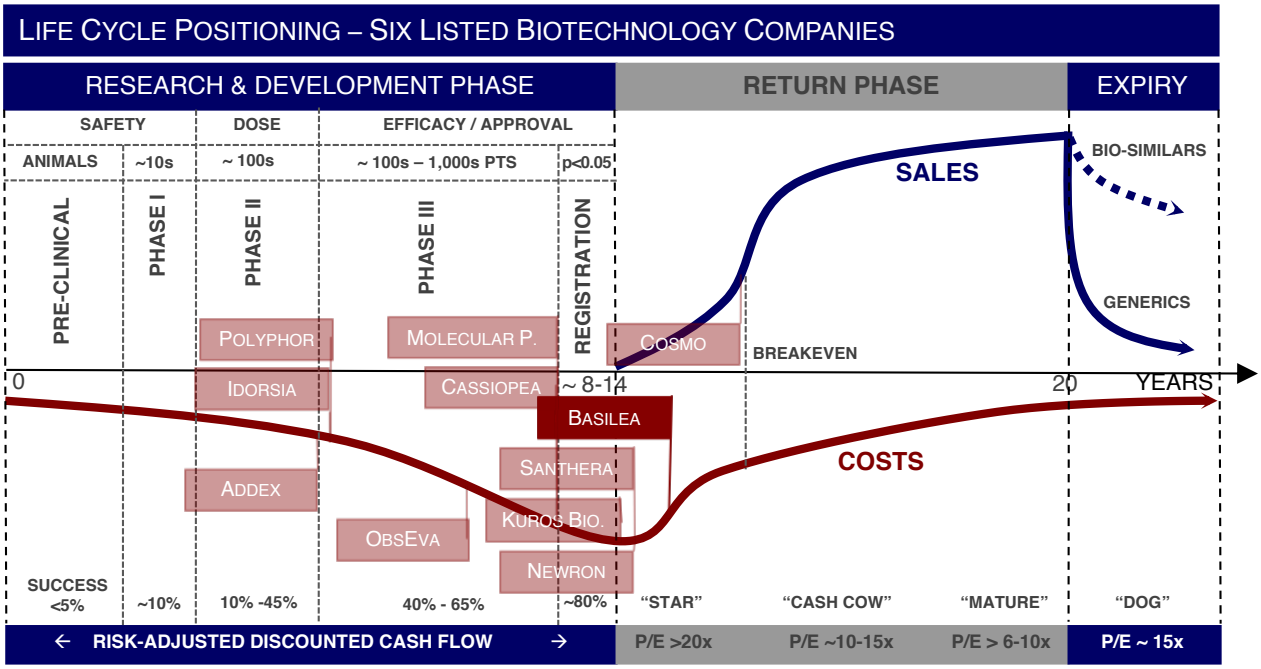
In December 2015 Basilea successfully placed a CHF 200 mn senior unsecured convertible bond with an annual coupon of 2.75% (payable semi-annually in arrear, with a 30%-premium conversion price of CHF 126.10 per share and maturity in December 2022). The proceeds, together with cash on hand, will be used 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.

Basilea has sufficient cash to approach profitability expected in 2020/2021

Basilea should have sufficient cash to fund its key development plans, reach profitability we expect in 2020/2021 and repay its CHF 200 mn convertible bond in December 2022 with a gross cash position including financial investments of CHF 178 mn (30 June 2019), in our view. The BARDA contract is worth up to USD 128 mn of funding for Zevtera's US pivotal trials or approximately 70% of the development costs. Assuming an operating loss of CHF 22-27 mn in FY 2019 as guided by Basilea, a lower operating loss in FY 2020 of around CHF 25 mn based on our estimates, Basilea has sufficient cash to approach profitability in 2020/2021. Further upside to the company's cash position could come from a licensing deal with a US partner for Zevtera, and from licensing deals of derazantinib or its earlier stage oncology projects. Initial efficacy signals of the tumor checkpoint controller BAL101553 in glioblastoma (brain cancer) or ovarian cancer patients in 2019/2020 could trigger a lucrative partnering agreement with a major cancer player. Moreover, the Pfizer transaction provides Basilea financial flexibility to expand its R&D pipeline.

Life Cycle Positioning – Medium Risk

We qualify an investment in Basilea as Medium Risk. The company has a sizeable gross cash position and a BARDA contract worth up to USD 128 mn in funding, which should be sufficient to reach profitability, thanks to increasing revenues from Cresemba and Zevtera through extensive partner and distribution agreements enhancing their global reach. Additionally, upfront payments from a potential development and commercialization partnering deal for Zevtera in the US, as well as for the early stage oncology projects could boost Basilea's cash position further. (See Important Disclosures for our Risk Qualification).



SOURCE: VALUATIONLAB

Valuation Overview

Sum-of-parts risk-adjusted NPV (rNPV) points to a fair value of CHF 126 per share
We derive a sum-of-parts rNPV of CHF 126 per share for Basilea, with estimated gross cash of CHF 16 per share (30 June 2019) and overhead expenses of CHF 17 per share (including annual overhead expenses and the CHF 200 mn convertible bond repayment in 2022), 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
CRESEMBA (ISAVUCONAZOLE)	MOLD INFECTIONS (ASPERGILLUS)	806	2015/16	85	100%	**85**	60%
ZEVTERA (EU/ROW)	LUNG INFECTIONS	103	2015	12	100%	**12**	9%
ZEVTERA (GLOBAL)	BACTEREMIA	227	2022	27	72.5%	**20**	14%
ZEVTERA (GLOBAL)	SEVERE SKIN INFECTIONS	102	2022	9	72.5%	**7**	5%
DERAZANTINIB (PANFGFR INH.)	INTRAHEPATIC CHOLANGIOCARCINOMA	115	2023	5	50%	**3**	2%
BAL101553 (CHECKPOINT CTRL.)	TREATMENT-RESISTANT TUMORS	517	>2023	31			
BAL3833 (PANRAF/SRC INH.)	TREATMENT-RESISTANT TUMORS	498	>2023	44			
GROSS CASH (INCL. CHF 200 MN CONVERTIBLE BOND) (30 JUNE 2019)		178		16		**16**	11%
TOTAL ASSETS				230		**143**	**100%**
OVERHEAD EXPENSES (INCL. REPAYMENT OF CHF 200 MN CONVERTIBLE BOND DUE 2022)				-17		**-17**	
NPV/SHARE (CHF)				213		**126**	
SHARE PRICE ON SEPTEMBER 15, 2019						46.1	
PERCENTAGE UPSIDE / (DOWNSIDE)						174%	

* NOTE: 10.88 MN SHARES USED FOR CALCULATION NPV/SHARE AS WE ASSUME BASILEA WILL PAY BACK THE CHF 200 MN CONVERTIBLE BOND IN 2022 (INCLUDED IN OVERHEAD EXPENSES)
NOTE: 11.88 MN SHARES OUTSTANDING INCLUDES 1 MN TREASURY SHARES RESERVED FOR POTENTIAL CONVERSION OF THE CONVERTIBLE BOND
ESTIMATES AS OF 16 SEPTEMBER, 2019 SOURCE: VALUATIONLAB ESTIMATES

Cresemba (invasive mold infections) - NPV of CHF 85/share
We forecast peak sales forecast for Cresemba to amount to CHF 800+ mn, which reflect the excellent sales uptake in the US by partner Astellas, next to Pfizer's marketing muscle and dominant presence in anti-infectives. Cresemba was first launched in the US in early 2015 by partner Astellas Pharmaceuticals. The EU rollout started in Q1 2016, by the same contract field force provided by Quintiles that launched Zevtera in core Europe. Distributors, which also sell Zevtera, were contracted for other countries/regions. With the conclusion of the Pfizer licensing agreement, Pfizer now markets and books sales of Cresemba in Europe (excl. the Nordics), Russia, Turkey, Israel, China and Asia Pacific in return for regulatory and sales milestones and mid teen royalties on sales. Asahi Kasei has Japanese rights with a potential launch in 2022. We calculate an NPV of CHF 85 per share for Cresemba in treating invasive mold infections including aspergillosis and mucormycosis in adults.

Zevtera (lung infections – EU/ROW) - NPV of CHF 12 per share
Late 2013, Zevtera was approved to treat hospital lung infections in the EU. In 2015 and 2016, the antibiotic was rolled out in the core European markets by the contract field force provided by Quintiles. Correvio (formerly Cardiome) is now responsible for commercialization in Europe and Israel, while CR Gosun will develop and commercialize Zevtera in China, Hong Kong and Macao, following distribution agreements signed in September 2017. We expect global peak product sales in lung infections to amount to CHF 100+ mn with a NPV of CHF 12 per share.

Zevtera (new US development plans) – rNPV of CHF 27/share
Zevtera enjoys QIDP (Qualified Infectious Disease Product) status in the US for the potential use in community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI), and Staphylococcus aureus bacteremia (SAB) bloodstream

infections. Zevtera now enjoys at least 10 years US market exclusivity in these indications upon approval. In April 2017, Basilea gained Special Protocol Assessment (SPA) for two cross-supportive phase III trial protocols for ABSSSI ("TARGET" trial) and SAB ("ERADICATE" trial). Funding of up to USD 128 mn was secured by the BARDA contract in April 2016. In August 2019, positive results of the "TARGET" pivotal trial in ABSSSI were announced. As a result, we conservatively assume a 72.5% blended success rate for the US clinical development of Zevtera, the average of a general 65% (phase III) success rate for the "ERADICATE" pivotal trial in SAB and an 80% (filing) success rate for the positive "TARGET" pivotal trial in skin infections. Both cross-supportive pivotal trials are needed for US filing and approval.

Each indication provides considerable upside:

- **Staphylococcus aureus bacteremia (global) – rNPV of CHF 20/share**
- **Severe skin infections (global) – rNPV of CHF 7/share**

Derazantinib (iCCA) – rNPV of CHF 3/share

We forecast peak sales of derazantinib of CHF 100+ mn in intrahepatic cholangiocarcinoma (iCCA - a form of bile duct cancer) alone, with a rNPV of CHF 3 per share with a 50% (registrational phase II) success rate. Worldwide rights (excluding China, Hong Kong, Macau and Taiwan) for derazantinib (ARQ 087) were licensed from ArQule in April 2018. Derazantinib is a novel oral panFGFR (fibroblast growth factor receptor) inhibitor that targets various solid tumors, including intrahepatic cholangiocarcinoma, bladder, breast, gastric and lung cancer, where FGFR alterations range between 5-30%. In 2017, ArQule started a registrational phase II trial in intrahepatic cholangiocarcinoma (iCCA), a rare orphan disease where ODD (orphan drug designation) was granted in the EU and US. ODD provides 7-years (US) and 10-years (EU) marketing exclusivity upon approval. In January 2019, positive interim results of this trial were reported with promising efficacy in patients with iCCA. Top line results are expected in mid 2020. Basilea expects to run a phase III trial to achieve both EU and US approval, which may complete in 2022. ArQule received a USD 10 mn upfront payment from Basilea and is eligible to regulatory and sales milestones of up to USD 326 mn as well as staggered single to double-digit sales royalties. We assume Basilea seeks a commercialization partner upon successful completion of phase III development in iCCA in return for higher upfront and commercialization milestones and sales royalties. Partnering could occur earlier if the registrational phase II trial results are sufficient for US accelerated approval for iCCA or on demonstrable proof-of-concept in large cancer indications.

Due to the lack of POC, we have not included sales forecasts for advanced urothelial cancer, where Basilea started a POC trial of derazantinib alone or in combination with Roche's Tecentriq in August 2019.

Currently no value attributed to early stage pipeline projects

We have not accounted for Basilea's early stage projects due to the current lack of clinical proof-of-concept. The unadjusted NPV in the Sum of Parts table provides a "sneak preview" on what the value could be if our assumptions are reached.

BAL101553 (treatment-resistant tumors) - Phase I/IIa; launch >2023

BAL101553 is a so-called tumor checkpoint controller, which is being investigated for use in patients with advanced solid tumors. The drug targets amongst other markets, the USD 3.5

bn taxane market where there is an increasing need for new agents in taxane-resistant cancer patients. As BAL101553 passes the blood brain barrier and has oral bioavailability, there is also potential in glioblastoma (aggressive brain cancer). BAL101553 is available in an intravenous (IV) and oral formulation. The 2-hour IV formulation successfully completed phase I dose-escalation. Data of the phase IIa trial for the IV formulation was announced at ASCO in June 2016 showing signals of activity. Based on the promising data, Basilea initiated a phase I/IIa continuous (48-hour IV) infusion trial with portable pumps in September 2016, which could provide additional administration flexibility beyond daily oral administration and weekly 2-hour IV infusion.
In June 2015, Basilea also started a phase I/IIa trial of an oral formulation of BAL101553 in patients with advanced solid tumors and expanded the trial with an additional treatment arm for adult patients with advanced brain cancer (glioblastoma) in December 2016. Complete enrollment of the phase I part of the trial occurred in August 2019. In 28 patients with recurrent glioblastoma an MTD (maximum tolerated dose) was established at 30 mg (doses up to 25 mg/day were well tolerated) with 1 long-lasting responder with EB-1 (plus-end binding protein) biomarker still on treatment, while 5 other patients experienced stable disease. EB1 is located on the microtubules and involved in microtubule dynamics and is predictive of response to BAL101553 in mouse models. Strong EB1 staining was observed in the long-lasting responder with treatment ongoing for more than 15 months with an approximately 70% reduction in GBM tumor size. The potential use of EB1 to support a biomarker-driven clinical trial program is being assessed.
Additionally, the Adult Brain Tumor Consortium (NCI funded) started a phase I trial in newly diagnosed glioblastoma patients in January 2018. Early efficacy signals in recurrent glioblastoma and ovarian cancer in a phase IIa expansion trial could trigger a lucrative partnering agreement with a major cancer player. Peak sales could easily reach CHF 500+ mn or even more if the compound proves to provide clinical benefit in multiple indications.

BAL3833 (treatment-resistant tumors) - Phase I; launch >2023
In July 2015 Basilea in-licensed BAL3833, a novel panRAF/SRC inhibitor from a consortium of UK organizations for undisclosed terms. A phase I dose-escalation trial in advanced solid tumor patients was started in May 2015. Basilea's partner, the Institute of Cancer Research has now completed enrollment of the phase I dose-escalation trial. A maximum tolerated dose (MTD) was not defined. The current formulation of BAL3833 will not be continued based on the pharmacokinetic profile. Basilea is conducting pre-clinical activities to explore alternative formulations. BAL3833 is targeted to treat tumors that do not respond to or have developed resistance to currently available BRAF kinase inhibitors, such as Roche's Zelboraf or Novartis' Tafinlar, as well as RAS-driven tumors. The drug has the potential to offer new treatment options for melanoma (aggressive skin cancer) and other cancers, including colorectal, lung cancer and pancreatic cancer. Peak sales could easily reach CHF ~500 mn.

Sensitivities that can influence our valuation

Patent & market exclusivity: Cresemba's COM (composition of matter) patent expires in 2020 with the option for 5 years Hatch Waxman patent extension in the US and under similar provisions in other key markets. 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 market exclusivity can be added to the ODD exclusivity providing a total of 12 years exclusivity from approval in the US. Zevtera exclusivity lasts until end 2024 in the EU consisting of COM patent (mid-2019), 5 years SPC (supplementary protection certificate) and 1-year extension on regulatory exclusivity on new substantial indication (e.g. bacteremia). In the US, Zevtera received QIDP designation for the treatment of lung, skin and bloodstream infections resulting in 10 years 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, as well as the terms may differ. Commercialization of Cresemba in the US through Astellas is more straightforward, although here too uptake and terms may differ.

Pricing and reimbursement: After the formal approvals of Zevtera and Cresemba in the EU, the drugs must be priced and reimbursed by local healthcare providers on a country-by-country basis. In the US pricing and reimbursement is quite straightforward. Outside the US pricing and reimbursement occurs on a country-by-country base, which can lead to different pricing and reimbursement levels and timings.

Antimicrobial stewardship: A shift towards antimicrobial stewardship may influence current prescriber behavior for antibiotics. This is the 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 major 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 (PER SHARE)
2019					
7 JAN			FY 2018 PRELIMINARY REVENUE	HIGHER-THAN-EXPECTED FY 2018 PRELIMINARY (UNAUDITED) REVENUE OF CHF ~133 MN UP 31% (FY 2018 GUIDANCE: CHF 120-130 MN) WITH CHF ~82 MN REVENUES FROM CRESEMA & ZEVTERA UP 56% (FY 2018 GUIDANCE: CHF 75-85 MN); CASH OF CHF ~223 MN AT YEAR-END	
9 JAN	DERAZANTINIB	ICCA*	INTERIM ANALYSIS	INTERIM ANALYSIS (IN 40 PATIENTS) OF THE PHASE II REGISTRATIONAL BIOMARKER-DRIVEN TRIAL EXPECTED TO ENROLL ~100 PATIENTS WITH ICCA	
24 JAN	DERAZANTINIB	UROTHELIAL CANCER	ROCHE COLLABORATION	CLINICAL SUPPLY AGREEMENT WITH ROCHE TO EXPLORE DERAZANTINIB WITH OR WITHOUT ROCHE'S PD-L1 INHIBITOR TECENTRIQ (ATEZOLIZUMAB) IN PATIENTS WITH UROTHELIAL CANCER; ROCHE PROVIDES TECENTRIQ FREE OF COST	
7 FEB			MANAGEMENT COMMITTEE CHANGE	ADESH KAUL (CHIEF CORPORATE DEVELOPMENT OFFICER) TO SUCCEED DONATO SPOTA AS CHIEF FINANCIAL OFFICER AT AGM ON APRIL 10TH	
8 FEB	CRESEMBA	MOLD INFECTIONS	MILESTONE CRESEMBA	STRONG EUROPEAN CRESEMBA SALES BY PFIZER TRIGGER FIRST SALES MILESTONE PAYMENT OF USD 5 MN TO BASILEA	
19 FEB			FY 2018 RESULTS	TOTAL REVENUE +31% TO CHF 133 MN, CRESEMBA AND ZEVTERA REVENUE +56% TO CHF 82 MN; YEAR-END CASH CHF 223 MN; FY 2019 GUIDANCE: TOTAL REVENUES OF CHF 128-138 MN, CRESEMBA AND ZEVTERA REVENUE OF CHF 100-110 MN, OPEX SIMILAR TO FY 2018, OPERATING LOSS OF CHF 20-30 MN	
10 APR			AGM	ALL RESOLUTIONS PROPOSED BY BOARD APPROVED BY SHAREHOLDERS INCLUDING THE RENEWAL OF THE AUTHORIZATION TO INCREASE THE SHARE CAPITAL UP TO CHF 2 MN UNTIL APRIL 2021	
13-16 APR	CRESEMBA/ZEVTERA	ANTIFUNGAL/ANTIBIOTIC	ECCMID	BROAD RANGE OF POSTERS AND PRESENTATIONS AT ECCMID (EUROPEAN CONGRESS OF CLINICAL MICROBIOLOGY AND INFECTIOUS DISEASES) INCLUDING CRESEMBA PEDIATRIC TRIAL AND OPEN-LABEL TRIAL OF CRESEMBA PROPHYLAXIS AGAINST INVASIVE FUNGAL INFECTION IN ADULT PATIENTS UNDERGOING ALLOGENIC HEMATOPIETIC STEM CELL TRANSPLANTATION	
2 MAY	CRESEMBA	MOLD INFECTIONS	LAUNCH CANADA	AVIR PHARMA LAUNCHED CRESEMBA IN CANADA TRIGGERING AN UNDISCLOSED REGULATORY MILESTONE PAYMENT TO BASILEA	
1 JUL	DERAZANTINIB	ICCA*	ICCA TRIAL EXPANSION	EXPANSION OF ONGOING REGISTRATIONAL ICCA TRIAL IN OTHER FGFR GENE ABERRATIONS	
6 AUG	ZEVTERA	ABSSSI**	"TARGET" PHASE III RESULTS	POSITIVE TOP LINE RESULTS OF "TARGET" PHASE III TRIAL IN 679 PATIENTS WITH ABSSSI TO SUPPORT US REGISTRATION	
13 AUG	DERAZANTINIB	UROTHELIAL CANCER	START PHASE I/II	START BIOMARKER-DRIVEN MULTI-COHORT PHASE I/II TRIAL OF DERAZANTINIB WITH OR WITHOUT ROCHE'S TECENTRIQ IN PATIENTS WITH ADVANCED UROTHELIAL CANCER AND CONFIRMED FGFR GENOMIC ABERRATIONS	
21 AUG			H1 2019 RESULTS	H1 2019 RESULTS: CRESEMBA AND ZEVTERA REVENUE UP 91% TO CHF 53 MN, CASH CHF 178 MN (30 JUNE 2019); FY 2019 GUIDANCE: TOTAL REVENUE CHF 128-133 MN (FROM CHF 128-138 MN), CRESEMBA AND ZEVTERA REVENUE CHF 105-110 MN (FROM CHF 100-110 MN), OPERATING LOSS CHF 22-27 MN (FROM CHF 20-30 MN), NET OPERATING CASH CONSUMPTION CHF 60-65 MN (FROM CHF 55-65 MN)	
27 AUG	BAL101553 (ORAL)	GLIOBLASTOMA (BRAIN CANCER)	PHASE I	COMPLETE ENROLMENT PHASE I DOSE ESCALATION TRIAL OF DAILY ORAL BAL101553 IN 28 PATIENTS WITH RECURRENT GLIOBLASTOMA (UK TRIAL) WITH MAXIMUM TOLERATED DOSE ESTABLISHED AT 30 MG, DOSES UP TO 25 MG/DAY WERE WELL TOLERATED, 1 LONG-LASTING RESPONDER WITH EB-1 BIOMARKER STILL ON TREATMENT, 5 OTHER PATIENTS EXPERIENCED STABLE DISEASE	
YEAR-END	BAL101553 (IV)	GLIOBLASTOMA & OVARIAN CANCER	PHASE IIA RESULTS	TOP LINE RESULTS OF PHASE IIA EXPANSION TRIAL WEEKLY 48-HOUR INFUSION IN RECURRENT GLIOBLASTOMA OR PLATINUM-RESISTANT OVARIAN CANCER (CH TRIAL)	+CHF 8
2020					
H1	DERAZANTINIB	ICCA*	PHASE II	COMPLETE PATIENT ENROLMENT IN PHASE II REGISTRATIONAL BIOMARKER-DRIVEN ICCA TRIAL	
H2	BAL101553 (ORAL)	GLIOBLASTOMA (BRAIN CANCER)	PHASE I TRIAL (ABTC)	COMPLETE ENROLMENT OPEN-LABEL ORAL PHASE I TRIAL IN NEWLY DIAGNOSED GLIOBLASTOMA PATIENTS IN COLLABORATION WITH ABTC, WHERE ABTC CONDUCTS THE TRIAL AND BASILEA PROVIDES BAL101553 (US TRIAL)	
H2	DERAZANTINIB	UROTHELIAL CANCER	INTERIM DATA	INTERIM DATA FROM FIRST COHORT(S) OF PHASE I/II TRIAL OF DERAZANTINIB AND ROCHE'S TECENTRIQ IN ADVANCED UROTHELIAL CANCER	
H2	DERAZANTINIB	ICCA*	PHASE II	TOPLINE RESULTS OF THE PHASE II REGISTRATIONAL BIOMARKER-DRIVEN TRIAL; POTENTIAL FOR US ACCELERATED APPROVAL IN ICCA	+CHF 1
H2	DERAZANTINIB	ICCA*	INTERIM DATA	INTERIM DATA FROM ICCA EXPANSION TRIAL IN OTHER FGFR GENE ABERRATIONS	
	BAL101553	RESISTANT SOLID TUMORS	PARTNERING	POTENTIAL PARTNER AGREEMENT AFTER POC FULLY COMPLETED - BASILEA WILL NOT CONDUCT PHASE III TRIALS WITHOUT A PARTNER	
2021					
	CRESEMBA	MOLD INFECTIONS	PHASE III RESULTS	TOP LINE RESULTS OF JAPANESE PHASE III REGISTRATIONAL TRIAL CONDUCTED BY ASAHI KASEI	
H2	ZEVTERA	SAB***	"ERADICATE" PHASE III RESULTS	TOP LINE RESULTS US "ERADICATE" PHASE III TRIAL IN ~390 PATIENTS WITH SAB; POTENTIAL TO TRIGGER A LUCRATIVE US COMMERCIALIZATION AGREEMENT	+CHF 10

*ICCA = INTRAHEPATIC CHOLANGIOCARCINOMA (FORM OF BILE DUCT CANCER); **ABSSSI = ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS; ***SAB =STAPHYLOCOCCUS AUREUS BACTEREMIA

ESTIMATES AS OF 16 SEPTEMBER, 2019

SOURCE: VALUATIONLAB ESTIMATES

Technology & Pipeline

Uniquely positioned to address threat of resistance through integrated operations
Basilea's technology platform targets innovative treatments addressing drug resistance and non-response to current therapies in the key areas of infectious disease and oncology. 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 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 of supply for pre-clinical and clinical trials.

All required discovery technologies in-house to advance projects rapidly
Basilea has all the required technologies and skills to efficiently carry out drug discovery programs from target identification, lead finding, lead optimization to final clinical candidate selection. Core strengths are in biochemistry, microbiology, cancer biology, analytics, medicinal chemistry and discovery informatics. Basilea's wholly owned subsidiary in China supports the company's key R&D projects with chemical synthesis, analytical development and process research and development.

Outsourcing & partnering when needed, but oversight & coordination kept in-house
Basilea outsources many of its clinical development to CRO's (contract research organizations) to minimize fixed costs and retain resource flexibility. Oversight and overall coordination of these activities is 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, allows:

- Qualified decision making from early discovery all the way 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 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 a differentiated portfolio with potential best-in-class or first-in-class compounds for treating severe, resistant bacterial hospital infections; invasive hospital fungal infections with high mortality rates; and developing drugs to treat cancers that do not or no longer respond to current treatment options.

Differentiated R&D portfolio addressing bacterial & fungal infections, and cancer

PRODUCT PIPELINE

PRODUCT	DRUG CLASS	INDICATION	STATUS	LAUNCH DATE (EXPECTED)	PARTNER	PEAK SALES POTENTIAL
CRESEMBA (ISAVUCONAZOLE)	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 800+ MN
ZEVTERA (CEFTOBIPROLE)	BROAD-SPECTRUM CEPHALOSPORIN	LUNG INFECTIONS	MARKETED (EU) PHASE III (US) TBD	2014 (EU) 2017/2018 (ROW)	DISTRIBUTORS (ROW)	CHF 100+ MN
ZEVTERA (CEFTOBIPROLE)	BROAD-SPECTRUM CEPHALOSPORIN	BACTEREMIA (BLOOD STREAM INFECTIONS)	PHASE III	2022 (US/EU)	BARDA CONTRIBUTES TO PHASE III FUNDING FOR US	CHF 200+ MN
ZEVTERA (CEFTOBIPROLE)	BROAD-SPECTRUM CEPHALOSPORIN	SERIOUS (RESISTANT) SKIN INFECTIONS	PHASE III	2022 (US)	BARDA CONTRIBUTES TO PHASE III FUNDING FOR US	CHF 100+ MN
DERAZANTINIB (ARQ 087)	PANFGFR INHIBITOR	INTRAHEPATIC CHOLANGIOCARCINOMA (FORM OF BILE DUCT CANCER)	REGISTRATIONAL PHASE II TRIAL	2023	LICENSED FROM ARQULE PARTNER AFTER PHASE III	CHF 100+ MN
BAL101553	TUMOR CHECKPOINT CONTROLLER	REFRACTORY SOLID TUMORS	PHASE IIA (IV) PHASE I (ORAL)	>2023	PARTNER AFTER PHASE II	CHF 500+ MN
BAL3833	PANRAF KINASE INHIBITOR	REFRACTORY SOLID TUMORS	PHASE I	>2023	PARTNER AFTER PHASE II	CHF ~500 MN

ESTIMATES AS OF 16 SEPTEMBER, 2019 SOURCE: VALUATIONLAB ESTIMATES, BASILEA PHARMACEUTICA

Basilea's key products include:

1. **Cresemba (isavuconazole):** a novel triazole antifungal to treat invasive hospital fungal infections; approved and marketed by partner Astellas in the US; approved and initially marketed in the EU by the dedicated field force with Quintiles, Pfizer now has responsibility for manufacturing and commercialization in Europe (excluding the Nordics), Russia, Turkey, Israel, which was expanded to China and Asia Pacific; Asahi Kasei has Japanese rights (approval expected in 2022)
2. **Zevtera (ceftobiprole):** a 5th generation cephalosporin antibiotic that treats severe (resistant) bacterial hospital infections; approved and initially marketed in European countries for treating lung infections by a dedicated field force with Quintiles, In September 2017, Correvio (formerly Cardiome) received the commercialization rights for Europe (excluding the Nordics) and Israel, and has now taken over responsibility; CR Gosun will develop and commercialize in China, Hong Kong and Macao; Basilea is investigating additional indications including Staphylococcus aureus bacteremia (SAB – blood stream infection) and acute bacterial skin and skin structure infections (ABSSSI – positive phase III results in August 2019) with the goal to obtain US approval and potential label extensions outside of the US.
3. **Derazantinib:** an oral small molecule panFGFR (fibroblast growth factor receptor) inhibitor targeting various cancers with FGFR alterations including intrahepatic cholangiocarcinoma, bladder, breast, gastric and lung cancer; in-licensed worldwide rights (excluding China, Hong Kong, Macau and Taiwan) from ArQule in April 2018; registrational phase II trial in the orphan disease indication intrahepatic cholangiocarcinoma (iCCA) started in 2017; POC trial in advanced urothelial cancer alone or in combination with Roche's Tecentriq started in August 2019.
4. **BAL101553 (IV & oral):** a so-called tumor checkpoint controller with an IV and oral formulation for treating resistant tumors, including taxane-resistant cancers; potential use in brain cancer (glioblastoma); phase I/IIa trial daily oral BAL101553 includes glioblastoma patients; phase IIa expansion continuous pump (48-hour infusion) trial includes glioblastoma and ovarian cancer patients with top line results due by year-end 2019 (potential trigger lucrative partnering deal with a major cancer player); ABTC phase I trial daily oral BAL101553 in newly diagnosed glioblastoma.
5. **BAL3833:** an orally available small molecule panRAF/SRC kinase inhibitor targeting melanoma (aggressive skin cancer) and potentially other solid tumors such as ovarian or colorectal cancer; in-licensed in July 2015 from a UK consortium of organizations; a phase I dose-escalation trial started in 2015, enrollment completed in 2018; no maximum tolerated dose defined, analysis of data ongoing.

Forecasts & Sensitivity Analysis

Zevtera (lung, skin & blood stream infections)

Product Analysis

Zevtera all indications - rNPV of CHF 39 per share

1) Lung infections (EU/ROW): NPV of CHF 12/share; we forecast global peak product sales (excluding the US) of CHF 103 mn. Zevtera was launched in early 2015 in the EU, with market exclusivity until at least 2024, a 10-days treatment price per patient of CHF 1,800 (European markets) and CHF 900 (ROW, excl. US), and a market penetration peaking at around 3%. In Europe and ROW (excl. US and China) we assume a distributor transfer price ranging between 35-55% of the wholesale price, and COGS ranging 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 conservatively CHF 43 mn in development and sales milestones. Our NPV amounts to CHF 133 mn or CHF 12 per share assuming a WACC of 7% (for details see page 27).

2) Bacteremia (global): rNPV of CHF 20/share: we forecast peak sales of CHF 227 mn with first launches in 2022 and the same EU market exclusivity as in severe skin infections and 10 years from launch in the US. We conservatively assume a 28-days treatment price of CHF 5,040 (Europe), CHF 2,520 (ROW), and USD 6,720 (US) per patient with market penetration peaking at 4-6%. We assume Basilea to seek a US commercialization partner on successful "ERADICATE" pivotal trial results of Zevtera in SAB expected in H2 2021, assuming USD 100 mn in upfront and sales milestones and 20% royalties on sales. Our rNPV amounts to CHF 213 mn or CHF 20 per share with a 72.5% blended success rate, the average success rate for SAB (65% phase III) and ABSSSI (80% filing) following the positive "TARGET" pivotal trial results announced in August 2019. Both cross-supportive pivotal trials are needed for US filing and approval (for details see page 28).

3) Severe skin infections (global): rNPV of CHF 7/share; we forecast peak sales of CHF 102 mn with a launch in 2022, the same market exclusivity as for bacteremia, a 7-days treatment price of CHF 1,260 (Europe), CHF 630 (ROW) and USD 1,680 (US), and market penetration peaking at ~2-4%. We assume the same US partner as for Zevtera in SAB with USD 50 mn in upfront and sales milestones and 20% royalties on sales. Our rNPV amounts to CHF 73 mn or CHF 7 per share with the same 72.5% blended success rate for SAB and ABSSSI (for details see page 29).

"TARGET" results a major milestone towards US approval

Basilea's hospital antibiotic Zevtera (ceftobiprole) provides physicians with a first-line simplified empiric treatment option in patients with hospital-acquired pneumonia thanks to its broad-spectrum activity and safety profile. The drug has excellent activity against resistant bacteria such as MRSA (methicillin-resistant Staphylococcus aureus), which is prevalent in many countries, as well as activity against Gram-negative pathogens. Zevtera is well suited to replace a combination of antibiotics often required to treat patients with lung infections with a single treatment option. Zevtera is currently approved in the major European countries and several non-European countries for the treatment of community-acquired bacterial pneumonia (CABP) and hospital-acquired bacterial pneumonia (HABP) in adults, excluding ventilator-associated bacterial pneumonia (VABP). Uptake has been slow as pricing, (regional) reimbursement and hospital formulary listing and inclusion in

microbial stewardship programs is typically lengthily in Europe, while prescribers tend to constrain use of novel antibiotics to avoid the buildup of resistance.

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

1) Increasing the global reach and rollout through partnerships and distribution deals
2) Accessing the lucrative US market though a phase III development program (largely paid by BARDA) – two cross-supportive phase III trials, "TARGET" for skin infections (positive results announced in August 2019) and "ERADICATE" in bacteremia (results due H2 2021) are needed for US approval

Correvio distribution agreement replaces the costly sales force in core Europe

Zevtera was initially marketed in Germany, France, Italy, the United Kingdom, Austria and Switzerland through a dedicated contract field force provided by Quintiles. In September 2017, signed a distribution agreement with the Canadian specialty pharma company Correvio (formerly Cardiome) for Zevtera in Europe and Israel. Under the terms of the agreement, Correvio has the right to commercialize Zevtera in more than 30 countries in Europe (excluding Nordic countries) and in Israel, effectively replacing the costly dedicated contract field force in the core European markets. Basilea received an upfront payment of CHF 5 mn and is eligible for undisclosed additional payments upon achievement of pre-specified regulatory and commercial milestones. Basilea will supply Correvio with the product at a transfer price (we assume transfer prices starting at 35% and eventually rising to 55%).

Agreement with CR Gosun for China, Hong Kong & Macao

At the end of September 2017, Basilea entered into another important license agreement. This was with Shenzhen China Resources Gosun Pharmaceutical Company, Ltd (CR Gosun) for Zevtera in China, Hong Kong and Macao. CR Gosun is granted an exclusive license to develop, manufacture and commercialize Zevtera in this territory, and will bear all the cost for regulatory and development activities including the conduct of clinical trial to obtain approval. Basilea will received an execution payment of CHF 3 mn and is eligible to receive up to approximately CHF 145 mn additional payments upon achievement of pre-specified regulatory and commercial milestones. Basilea will initially supply CR Gosun at a transfer price and will be eligible for tiered double-digit royalties on product sales once CR Gosun manufactures Zevtera itself.

Zevtera is now covered in over 80 countries by a network of distribution partners

In 2015, Basilea entered into a partnership with Hikma Pharmaceuticals for Zevtera in the Middle East and North Africa (MENA) region. A year later, the partnership was extended to include Cresemba. In 2016, further partnerships were announced in 19 Latin American countries with Grupo Biotoscana, and the Nordic countries with Unimedic Pharma covering Zevtera and Cresemba. In March 2018, Zevtera was launched in Argentina, the first launch of the hospital antibiotic in Latin America and outside Europe, by Grupo Biotoscana. In June 2017, Basilea signed a distribution agreement with Avir Pharma for Zevtera and Cresemba in Canada, which launched Zevtera in April 2018. As a result, Zevtera is now covered in over 80 countries worldwide through license and distribution agreements. In other geographies that refer to the approval in European countries, such as Russia/CIS, the company is in discussions with potential distribution partners.

Zevtera could become profitable in 2019 – US critical for commercial success
In 2019, we expect Zevtera product sales to amount to CHF ~13 mn as the drug achieves pricing, reimbursement and hospital formulary listing in more countries at substantial less costs than with the dedicated contract sales force in core European markets. As a result, we believe Zevtera in severe lung infections could become a profitable franchise as early as in 2019. However, the commercial success of Zevtera depends largely on the approval in the US. Roughly half of the USD 3.1 bn global anti-MRSA hospital antibiotic sales are generated in the US. Typically, the US market is responsible for 70-90% of branded hospital antibiotics.

US development of Zevtera provides a substantial return on investment at low risk
In 2018, Basilea started two-cross supportive phase III trials in severe skin infections and bacteremia (bloodstream infections) under Special Protocol Assessment (SPA) to gain US approval. Qualified Infectious Disease Product (QIDP) status effectively provides 10 years of market exclusivity in the US, while a USD 128 mn contract with the US Biomedical Advanced Research and Development Authority (BARDA) covers approximately 70% of the development costs. The anti-MRSA hospital antibiotics market is valued at USD 2.9 bn with the US being the most important region representing up to 90% of the global market for certain brands, for instance in the case of Merck & Co's Cubicin (daptomycin) before its patent expired. Therefore, we believe US development of Zevtera provides a substantial return on investment for Basilea at a relatively low risk. Specific historical success probabilities for antibiotics in phase III development typically range around 80%. We conservatively assume a 72.5% blended success rate for the US clinical development of Zevtera, the average of a general 65% (phase III) success rate for the "ERADICATE" pivotal trial in SAB and an 80% (filing) success rate for the positive "TARGET" pivotal trial in skin infections. Both cross-supportive pivotal trials are needed for US filing and approval.

US infectious disease incentive programs provide substantial exclusivity & upside
In August 2015 Zevtera received QIDP (Qualified Infectious Disease Product) status in the US for the potential use in community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI). Additionally, Zevtera received QIDP designation for Staphylococcus aureus bacteria (SAB) bloodstream infections in December 2017. If approved in any one of these three indications, Zevtera would be eligible for at least 10 years market exclusivity, consisting of 5 years NCE (new chemical entity) and another 5 years QIDP exclusivity. This provides sufficient time to make an attractive return on investment and provides substantial upside. Furthermore, if the US federal programs DISARM and ADAPT were to be implemented, these could provide additional incentives such as a more flexible, accelerated approval pathway with limited patient populations, and a value-based higher reimbursement price for Zevtera.

BARDA contract underlines value of US Zevtera development program
In April 2016, BARDA, the Biomedical Advanced Research and Development Authority, a division within the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response, signed a contract with Basilea for co-funding of the phase III clinical development of Zevtera, designed to receive US approval in treating life-threatening bacterial infections. BARDA provides an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies and diagnostic tools for public health medical emergencies and threats. Consequently, the BARDA contract underlines the relative importance and value of Zevtera in treating life-threatening, often resistant and difficult to treat bacterial infections, which are 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.

BARDA has provided funding of approximately USD 20 mn over an initial period of 18 months where Basilea has successfully gained agreement from the FDA on the development program for Zevtera, under SPA, in bacteremia and ABSSSI. As a result, BARDA awarded USD 54.8 mn additional funding for the conduct of two cross-supportive phase III trials in ABSSSI and SAB. BARDA may exercise further options, which would bring the total value of the contract up to USD 128 mn over a period of 4 1/2 years, upon successful completion of pre-defined milestones including pre-clinical, clinical, manufacturing and associated regulatory activities. With co-funding of the US Zevtera development program secured, a critical prerequisite to start the US Zevtera development program, Basilea now has the flexibility to sign on a US commercialization partner, likely at a later stage, e.g. after phase III results, with the potential of higher upfront and sales milestone payments and royalties on sales than we initially forecasted, providing considerable room to surprise positively.

US phase III development under SPA, largely paid by BARDA, started in early 2018
In April 2017 Basilea gained Special Protocol Assessment (SPA) for the cross-supportive phase III trial protocols for ABSSSI and Staphylococcus aureus bacteremia (SAB –blood stream 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 development risk, now the largest risk remaining. Basilea started US phase III development of Zevtera in February 2018 with the start of the phase III ABSSSI trial followed by the SAB trial in August 2018. Basilea started cross-supportive phase III trials as it has secured up to USD 128 mn funding through a contract with the BARDA in April 2016. US filing requires that both trials be completed.

1. **"ERADICATE" SAB phase III trial - started August 2018; launch 2022**
   The phase III trial of Zevtera in Staphylococcus aureus bacteremia (SAB- blood stream infections) named "ERADICATE" started in August 2018. This is a global, randomized, double blind, multicenter trial that is estimated to enroll approximately 390 patients. The trial compares Zevtera (500 mg, 2-hours infusion) to daptomycin (6 mg/kg, 30-minutes infusion – branded Cubicin by Merck & Co) for overall success in the treatment of SAB including endocarditis. Aztreonam (1,000 mg, 30-minutes infusion) can be added to daptomycin if the involvement of Gram-negative bacteria is suspected, which is not needed with Zevtera due to its broad spectrum of activity that also covers Gram-negative bacteria. The primary endpoint is the overall success rate at the post-treatment evaluation (PTE) visit (time frame: day 70 +/- 5) in the modified intent-to-treat (mITT) population. The blood stream infection trial is expected to take approximately three years to complete with topline results due in H2 2021. QIDP designation provides for priority review of 8 months, including filing time. Assuming filing in H2 2021, approval and launch could occur in 2022.

2. **"TARGET" ABSSSI phase III trial – positive results reported in August 2019**
   The 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 (see below). This was a global, randomized,

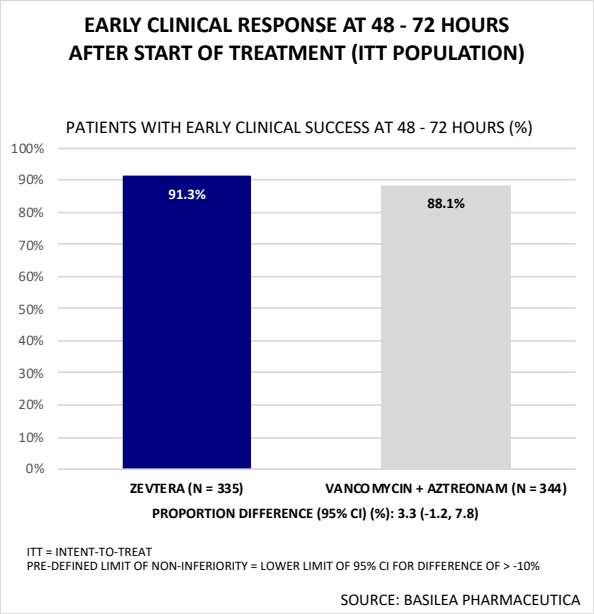
double blind, multicenter trial conducted in more than 30 clinical centers in the US and Europe that enrolled 679 patients. The trial compared Zevtera (500 mg, 3x daily 2-hours infusion) to comparator vancomycin (1,000 mg, 2-hours infusion) or vancomycin (15 mg/kg 2x daily 2-hours infusion) plus aztreonam (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 is early clinical response (time frame: 48 – 72 hours after start of drug treatment); and the main secondary endpoint is investigator assessed clinical success at the test of cure visit 15-22 days after randomization.

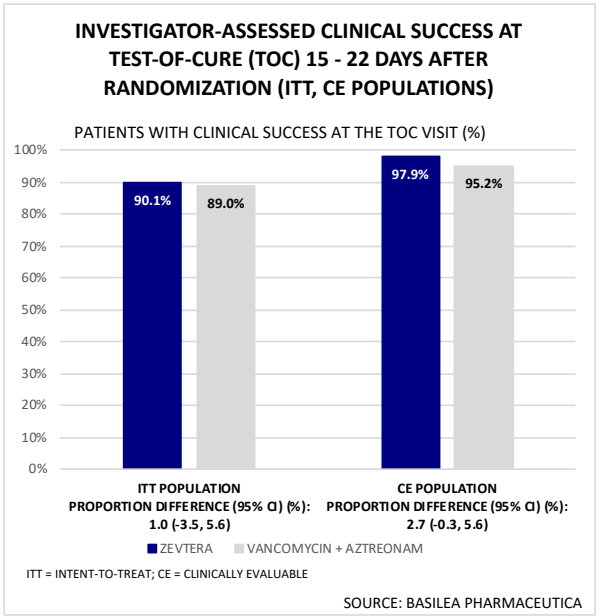
We conservatively assume a 72.5% blended success rate for the US clinical development of Zevtera, the average of a general 65% (phase III) success rate for the "ERADICATE" pivotal trial in SAB and an 80% (filing) success rate for the positive "TARGET" pivotal trial in skin infections. Both cross-supportive pivotal trials are needed for US filing and approval.

Halfway there! – Positive "TARGET" results a major milestone towards US filing

In the pivotal "TARGET" phase III trial Zevtera was non-inferior to vancomycin plus aztreonam for the treatment for 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 prespecified primary endpoint of early clinical response at 48 to 72 hours





after 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 baseline. Response rates were 91.3% with Zevtera versus 88.1% for vancomycin plus aztreonam.

Zevtera also met the prespecified 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.

Treatment-resistance bacteria an increasing challenge in hospitals with a 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 (ICU's). 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 that are resistant to hospital antibiotics, particularly MRSA (methicillin-resistant S. aureus) and multidrug-resistant (MDR) S. pneumoniae, are associated with poor outcomes and higher treatment cost 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 the 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, 50% in the US, and a staggering 59% 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. 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 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 antibiotic 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 well positioned to become a standard treatment in hospital pneumonia

We believe Zevtera is well positioned to become a standard treatment in hospitalized CABP and HABP (excluding VABP). 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 adds to it becoming a standard empiric treatment for hospital pneumonia.

COMPETITIVE POSITIONING BROAD-SPECTRUM ANTIBIOTICS

COMPOUND	KEY FEATURES					RELEVANT INDICATIONS
	GRAM-POSITIVE	MRSA	GRAM-NEGATIVE	PSEUDO-MONAS	SAFETY PROFILE	
ZEVTERA (CEFTOBIPROLE)						CAP, HAP
ZOSYN (PIPERACILLIN-TAZOBACTAM)						cSSSI, CAP, NP, cUTI, IAI
TEFLARO (CEFTAROLINE)						cSSI, CAP
VANCOMYCIN (GENERIC)						cSSI, LRI*
ZYVOX (LINEZOLID)						cSSSI, CAP*, NP*
COVERAGE (IN-VITRO ACTIVITY)	≥90%	60-89%	<60%	* IN COMBINATION WITH GRAM-NEGATIVE AGENTS		

SOURCE: VALUATIONLAB, BASILEA

Hospital antibiotics in Europe take time before revenues take off

Initial sales of hospital antibiotics in Europe typically show a gradual start and then accumulate steadily over time. This is because hospitals generally need to test the effectiveness of any new antibiotic against the pathogens prevalent in their hospital (so-called antimicrobial susceptibility testing). Additionally, hospitals want to balance the use of a new antibiotic - which they need due to ineffectiveness of current antibiotics - with too widespread use and the potential build-up of resistance to the new antibiotic. There is also the usual pricing and reimbursement discussion on a country-by-country basis in Europe. In some countries like Italy, not only national but even regional pricing and reimbursement is required too. National approval, pricing and reimbursement for Zevtera have now been established in several core European countries. We have accounted for this gradual, linear sales uptake with peak sales typically reached at the end of exclusivity.

First cephalosporin monotherapy for CABP & HABP in the EU

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:

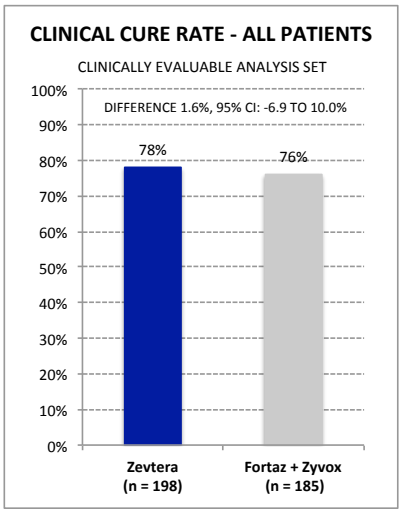
- For the primary endpoint in 469 clinically evaluable (CE) patients, cure rates were 86.6% for Zevtera versus 87.4% for ceftriaxone +/- Zyvox; in the ITT analysis of 638 CABP patients, these cure rates were 76.4% versus 79.3%, respectively.
- For the secondary endpoint of clinical cure in patients with 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 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. Primary outcome was clinical cure at the test-of-cure visit.

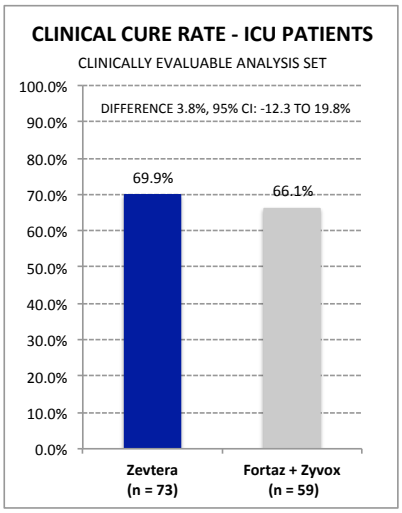
Zevtera proved non-inferiority compared to the Fortaz + Zyvox combination with comparable cure rates and microbiologically eradication rates, except in VABP patients where it was not non-inferior to the comparator. Hence, VABP patients are excluded in Zevtera's EU label. In summary:

- 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.



SOURCE: VALUATIONLAB, BASILEA



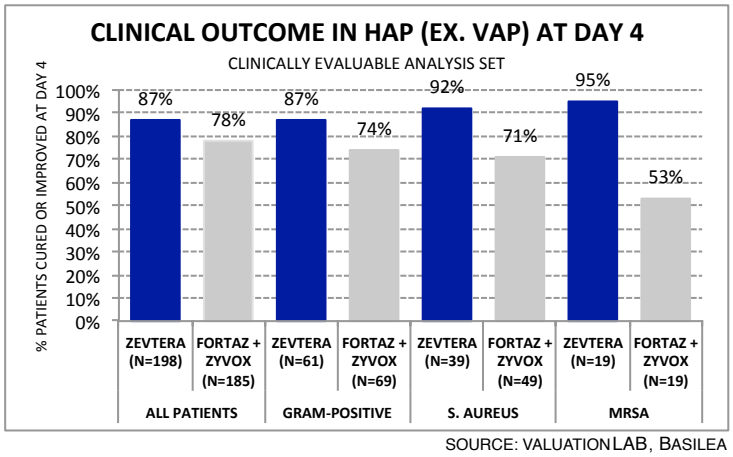
SOURCE: VALUATIONLAB, BASILEA

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 at 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 at 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 hospital earlier with a positive impact on overall treatment costs.



SOURCE: VALUATIONLAB, BASILEA

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) **Blood stream 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 the:

Europe (Correvio – distribution agreement)
ROW (distributors – distribution agreement)
China (CR Gosun – royalty agreement)
US (third party funding by BARDA announced in April 2016 – US commercialization partner to be announced prior to launch – we assume a royalty agreement).

We assume that the 2016 signed BARDA contract pays for roughly 70% of the US development costs. Market exclusivity in EU/ROW should last through 2024 with extensions for new indications such as ABSSSI and bacteremia, while Zevtera should enjoy US market exclusivity until 2032.

1) Lung infections – Risk-adjusted NPV of CHF 12 per share (page 27)

Europe: We believe peak product sales in Europe could amount to CHF 37 mn (or CHF 19 mn at transfer prices booked by Basilea), assuming a treatment price of CHF 1,800 per patient (assuming 10 days treatment, 3 vials per day at CHF 60 per vial), a penetration rate peaking at around 3%. With Correvio now responsible for distribution of Zevtera in Europe and Israel, Basilea will now ship product to Correvio at a transfer price. We assume the transfer price starting at 35% of the wholesale price and rising to 55% as Zevtera sales mature. Correvio makes its profit off the difference between the wholesale price and discounted transfer price. Basilea benefits from selling Zevtera through an established distribution channel with no other costs than COGS and taxes.

ROW (excl. US & China): Peak product sales in the ROW are expected to amount to CHF 33 mn (or CHF 17 mn at transfer prices booked by Basilea), assuming a significantly lower treatment price of CHF 900 per patient (CHF 30 per vial) a penetration rate of around 3%. Similar to the European markets, we assume Basilea sells Zevtera to its distributors in the ROW at a discounted transfer price using the same discount to the wholesale price.

China, Hong Kong, Macao: First launches by CR Gosun are expected in 2022 with peak sales expected to reach CHF 64 mn. In our forecasts we assume 12% royalties on sales and conservatively CHF 43 mn in development and sales milestones.

2) Severe blood stream infections – Risk-adjusted NPV of CHF 20/share (page 28)

Europe: Assuming a global launch in 2022, we believe peak product sales in Europe could amount to CHF 52 mn (or CHF 26 mn at transfer prices booked by Basilea), assuming a treatment price of CHF 5,040 per patient (conservatively assuming 28-days treatment, 3

vials per day at CHF 60 per vial), and a penetration rate conservatively peaking at around 4%.

ROW: Peak product sales in the ROW are expected to amount to CHF 40 mn (or CHF 20 mn at transfer prices booked by Basilea), assuming a significantly lower treatment price of CHF 2,520 per patient (CHF 30 per vial), with a similar peak penetration rate as in the European markets.

US: Peak product sales are expected to amount to around CHF 206 mn based on a treatment price of USD 6,720 per patient (USD 80 per vial) with a peak penetration conservatively amounting to around 6% in 2031, the last year before Zevtera loses its market exclusivity.

3) Severe skin infections – Risk-adjusted NPV of CHF 7 per share (page 29)

Europe: Assuming a global launch in 2022, we believe peak sales in Europe to amount to CHF 16 mn, assuming a treatment price of CHF 1,260 per patient (assuming 7 days treatment, 3 vials per day at CHF 60 per vial), a penetration rate peaking at around 2%, limited by market exclusivity that is assumed to last until 2024.

ROW: Peak sales in the ROW are expected to amount to CHF 8 mn in 2024, assuming a significantly lower treatment price of CHF 630 per patient (CHF 30 per vial) and a penetration rate peaking at around 1%.

US: Peak sales are expected to amount to CHF 102 mn based on a treatment price of USD 1,680 per patient (USD 80 per vial) with a peak penetration of around 4%, with market exclusivity up to 2032.

Forecasts & Sensitivity Analysis

ZEVTERA (CEFTOBIPROLE) - FINANCIAL FORECASTS FOR LUNG INFECTIONS

INDICATION	LUNG INFECTIONS (HOSPITAL AND COMMUNITY-ACQUIRED PNEUMONIA, EXCLUDING VENTILATOR-ASSOCIATED PNEUMONIA)
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 HAP** AND CAP*** (EXCL. VAP****) WITH GRAM NEGATIVE COVERAGE, INCL. PSEUDOMONAS

* MRSA = METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS; **HAP = HOSPITAL-ACQUIRED PNEUMONIA; ***CAP = COMMUNITY-ACQUIRED PNEUMONIA; ****VAP = VENTILATOR-ASSOCIATED PNEUMONIA

7Ps ANALYSIS

PATENT	EU: END 2024 = COMPOSITION OF MATTER (2019) + SPC (2024) + NEW US INDICATION (END 2024); US: 2031 = 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: CORREVIO NOW RESPONSIBLE; DISTRIBUTORS FOR OTHER REGIONS AT TRANSFER PRICE; CR GOSUN RESPONSIBLE FOR CHINA, HONG KONG, MACAO

REVENUE MODEL

EUROPE / REST OF WORLD - CORREVIO (FORMERLY CARDIOME)	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
NUMBER OF PATIENTS (MN)	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.9	1.9	1.9	2.0
GROWTH (%)	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
PATIENTS IN EUROPEAN MARKETS (MN)	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.8	0.8	0.8	0.8
PENETRATION (%)	1%	1%	1%	1%	2%	2%	3%	2%	2%	1%	1%
NUMBER OF PATIENTS TREATED	3'500	4'924	7'087	9'314	13'040	16'877	20'825	15'853	12'068	9'187	6'993
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)	6	9	13	17	23	30	37	29	22	17	13
TRANSER PRICE FOR CORREVIO (%)	35%	35%	40%	40%	45%	45%	50%	50%	55%	55%	55%
SALES EUROPEAN MARKETS (CHF MN)	**2**	**3**	**5**	**7**	**11**	**14**	**19**	**14**	**12**	**9**	**7**
PATIENTS IN DISTRIBUTOR REGIONS (MN)	1.0	1.0	1.0	1.1	1.1	1.1	1.1	1.1	1.1	1.2	1.2
PENETRATION (%)	0%	0%	1%	1%	2%	3%	3%	3%	2%	1%	1%
NUMBER OF PATIENTS TREATED	1'521	4'631	8'878	14'312	20'983	28'943	37'137	28'271	21'521	16'383	12'472
COST OF THERAPY PER PATIENT (CHF)	900	900	900	900	900	900	900	900	900	900	900
SALES DISTRIBUTOR REGIONS (CHF MN)	1	4	8	13	19	26	33	25	19	15	11
TRANSFER PRICE (%)	35%	35%	40%	40%	45%	45%	50%	50%	55%	55%	55%
SALES DISTRIBUTOR REGIONS (CHF MN)	**0**	**1**	**3**	**5**	**8**	**12**	**17**	**13**	**11**	**8**	**6**
SALES BOOKED BY BASILEA AT TRANSFER PRICE (CHF MN)	**3**	**5**	**8**	**12**	**19**	**25**	**35**	**27**	**23**	**17**	**13**
CHANGE (%)	-32%	70%	82%	43%	61%	33%	40%	-24%	-16%	-24%	-24%
UPFRONT & MILESTONE PAYMENTS (CHF MN)											
COGS (CHF MN)	-1	-2	-3	-4	-6	-8	-11	-8	-6	-5	-4
SG&A (CHF MN)	-2	-2	-2	-2	-2	-2	-2	0	0	0	0
PROFIT BEFORE TAX (CHF MN)	**-1**	**0**	**3**	**6**	**11**	**15**	**23**	**19**	**16**	**13**	**10**
TAX RATE (%)	0%	0%	0%	0%	0%	0%	0%	0%	20%	20%	20%
TAXES (CHF MN)	0	0	0	0	0	0	0	0	-3	-3	-2
PROFIT (CHF MN)	**-1**	**0**	**3**	**6**	**11**	**15**	**23**	**19**	**13**	**10**	**8**

CHINA, HONG KONG, MACAO - CR GOSUN	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
SALES (CHF MN)					**5**	**20**	**32**	**42**	**50**	**56**	**59**
ROYALTIES (~12%) (CHF MN)					1	2	4	5	6	7	7
UPFRONT & MILESTONE PAYMENTS (CHF MN)	1	1	1	3	6	1	2	3	4	4	4
PROFIT BEFORE TAX (CHF MN)	**1**	**1**	**1**	**3**	**6**	**4**	**6**	**8**	**10**	**11**	**11**
TAX RATE (%)	0%	0%	0%	0%	0%	0%	0%	0%	20%	20%	20%
TAXES (CHF MN)	0	0	0	0	0	0	0	0	-2	-2	-2
PROFIT (CHF MN)	**1**	**1**	**1**	**3**	**6**	**4**	**6**	**8**	**8**	**9**	**9**

	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
GLOBAL SALES (CHF MN)	**8**	**13**	**21**	**30**	**47**	**76**	**103**	**96**	**91**	**87**	**83**
CHANGE (%)	80%	70%	59%	43%	60%	61%	35%	-7%	-5%	-4%	-5%
GLOBAL PROFIT (CHF MN)	**0**	**1**	**4**	**8**	**17**	**19**	**29**	**27**	**21**	**19**	**17**
CHANGE (%)	-96%	-669%	271%	122%	109%	12%	55%	-9%	-22%	-11%	-10%

WACC (%)	7%
NPV TOTAL PROFIT (CHF MN)	**133**
NUMBER OF SHARES (MN)	10.9
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
	160	22	21	20	20	19	18	18
	140	19	18	18	17	17	16	16
	120	16	16	15	15	14	14	13
PEAK PRODUCT SALES (CHF MN)	100	13	13	13	**12**	12	12	11
	80	11	10	10	10	9	9	9
	60	8	8	8	7	7	7	7
	40	5	5	5	5	5	5	4

ESTIMATES AS OF 16 SEPTEMBER, 2019

SOURCE: VALUATIONLAB ESTIMATES

ZEVTERA (CEFTOBIPROLE) - FINANCIAL FORECASTS FOR BACTEREMIA

INDICATION	TREATMENT OF BACTEREMIA (SEVERE BACTERIAL BLOOD STREAM INFECTION)
DOSAGE	INTRAVENOUS INFUSION 3X DAILY 500 MG INFUSED OVER 2 HOURS FOR ~28 DAYS (HOSPITAL ADMINISTERED PRODUCT)
PRICE	TREATMENT PRICE PER PATIENT (28 DAYS TREATMENT): EU: CHF 5,040 (28X CHF 180/DAY) I US: USD 6,720 (28X USD 240/DAY) I ROW: CHF 2,520 (28X CHF 90/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 2024); US: 2032 = 5 YEARS NCE + 5 YEARS QIDP EXCLUSIVITY
PHASE	H1 2016: FILING PHASE III STUDY PROTOCOL; SPECIAL PROTOCOL ASSESSMENT ACQUIRED APR 2017; PHASE III "ERADICATE" TRIAL STARTED AUG 2018; RESULTS H2 2021
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

EUROPE / REST OF WORLD (US TRIALS REQUIRED)	**2018E**	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**
NUMBER OF PATIENTS (MN)	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.8	0.8	0.8	0.8
GROWTH (%)	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
PATIENTS IN EUROPEAN MARKETS (MN)	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
PENETRATION (%)	0%	0%	0%	0%	1%	3%	4%	3%	2%	1%	1%
NUMBER OF PATIENTS TREATED	0	0	0	0	2'869	8'738	10'347	7'876	5'996	4'564	3'475
COST OF THERAPY PER PATIENT (CHF)	5'040	5'040	5'040	5'040	5'040	5'040	5'040	5'040	5'040	5'040	5'040
SALES EUROPEAN MARKETS (CHF MN)	0	0	0	0	14	44	52	40	30	23	18
TRANSER PRICE FOR CARDIOME (%)	35%	35%	40%	40%	45%	45%	50%	50%	55%	55%	55%
SALES EUROPEAN MARKETS (CHF MN)	**0**	**0**	**0**	**0**	**7**	**20**	**26**	**20**	**17**	**13**	**10**
PATIENTS IN DISTRIBUTOR REGIONS (MN)	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.5	0.5	0.5	0.5
PENETRATION (%)	0%	0%	0%	0%	0%	2%	3%	4%	3%	2%	1%
NUMBER OF PATIENTS TREATED	0	0	0	0	0	8'738	13'303	15'753	11'992	9'129	6'949
COST OF THERAPY PER PATIENT (CHF)	2'520	2'520	2'520	2'520	2'520	2'520	2'520	2'520	2'520	2'520	2'520
SALES DISTRIBUTOR REGIONS (CHF MN)	0	0	0	0	0	22	34	40	30	23	18
TRANSFER PRICE (%)	35%	35%	40%	40%	45%	45%	50%	50%	55%	55%	55%
SALES DISTRIBUTOR REGIONS (CHF MN)	**0**	**0**	**0**	**0**	**0**	**10**	**17**	**20**	**17**	**13**	**10**
SALES BOOKED BY BASILEA AT TRANSFER PRICE (CHF MN)	**0**	**0**	**0**	**0**	**7**	**30**	**43**	**40**	**33**	**25**	**19**
CHANGE (%)						357%	44%	-7%	-16%	-24%	-24%
UPFRONT & MILESTONE PAYMENTS (CHF MN)											
COGS (CHF MN)	0	0	0	0	-2	-10	-13	-12	-9	-7	-5
PROFIT BEFORE TAX (CHF MN)	**0**	**0**	**0**	**0**	**4**	**20**	**30**	**28**	**24**	**18**	**14**
TAX RATE (%)	0%	0%	0%	0%	0%	0%	0%	0%	20%	20%	20%
TAXES (CHF MN)	0	0	0	0	0	0	0	0	-5	-4	-3
PROFIT (CHF MN)	**0**	**0**	**0**	**0**	**4**	**20**	**30**	**28**	**19**	**15**	**11**

UNITED STATES (PARTNER REQUIRED)	**2018E**	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**
NUMBER OF PATIENTS (MN)	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
GROWTH (%)	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
PENETRATION (%)	0%	0%	0%	0%	1%	2%	3%	4%	5%	5%	5%
NUMBER OF PATIENTS TREATED	0	0	0	0	2'391	7'281	12'318	17'503	22'842	25'760	27'899
COST OF THERAPY PER PATIENT (CHF)	6'524	6'750	6'750	6'750	6'750	6'750	6'750	6'750	6'750	6'750	6'750
PARTNER SALES (CHF MN)	**0**	**0**	**0**	**0**	**16**	**49**	**83**	**118**	**154**	**174**	**188**
CHANGE (%)						205%	69%	42%	31%	13%	8%
ROYALTY (%)	0%	0%	0%	0%	20%	20%	20%	20%	20%	20%	20%
ROYALTIES (CHF MN)	0	0	0	0	3	10	17	24	31	35	38
UPFRONT & MILESTONE PAYMENTS (CHF MN)	0	0	0	60	30	0	0	10	0	0	0
R&D COSTS (CHF MN)	-10	-8	-8	-5	0	0	0	0	0	0	0
PROFIT BEFORE TAX (USD MN)	**-10**	**-8**	**-8**	**55**	**33**	**10**	**17**	**34**	**31**	**35**	**37**
TAXES (CHF MN)	0	0	0	0	0	0	0	0	-6	-7	-8
PROFIT (CHF MN)	**-10**	**-8**	**-8**	**55**	**33**	**10**	**17**	**34**	**25**	**28**	**30**

	2018E	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**
GLOBAL SALES (CHF MN)	**0**	**0**	**0**	**0**	**31**	**115**	**169**	**198**	**215**	**220**	**223**
CHANGE (%)						276%	47%	17%	9%	2%	2%
GLOBAL PROFIT (CHF MN)	**-10**	**-8**	**-8**	**55**	**38**	**30**	**47**	**61**	**44**	**43**	**41**
CHANGE (%)	231%	-17%	0%	-788%	-32%	-21%	57%	32%	-28%	-3%	-3%

WACC (%)	7%	
NPV TOTAL PROFIT (CHF MN)	**293**	
NUMBER OF SHARES (MN)	10.9	
NPV PER SHARE (CHF)	**27**	
SUCCESS PROBABILITY	72.5%	(AVERAGE PHASE III (SAB) & FILING (ABSSI) SUCCESS RATE)
RISK ADJUSTED NPV PER SHARE (CHF)	**20**	

SENSITIVITY ANALYSIS

		WACC (%)						
	CHF/SHARE	5.5	6.0	6.5	7.0	7.5	8.0	8.5
	100%	30	29	28	27	26	25	24
	95%	28	27	26	26	25	24	23
	90%	27	26	25	24	23	23	22
	85%	25	24	24	23	22	21	21
SUCCESS PROBABILITY	80%	24	23	22	22	21	20	20
	75%	22	22	21	20	20	19	18
	72.5%	22	21	20	**20**	19	18	18
	70%	21	20	20	19	18	18	17
	65%	19	19	18	18	17	16	16

ESTIMATES AS OF 16 SEPTEMBER, 2019

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): EU: CHF 1,260 (7X CHF 180/DAY) I US: USD 1,680 (7X USD 240/DAY) I ROW: CHF 630 (7X CHF 90/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 2024); US: 2032 = 5 YEARS NCE + 5 YEARS QIDP EXCLUSIVITY
PHASE	SPECIAL PROTOCOL ASSESSMENT ACQUIRED APR 2017; POSITIVE TOPLINE RESULTS PHASE III "TARGET" TRIAL IN 679 PATIENTS WITH ABSSSI REPORTED AUG 2019
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

EUROPE / REST OF WORLD (US TRIALS REQUIRED)	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
NUMBER OF PATIENTS (MN)	3.2	3.2	3.3	3.4	3.4	3.5	3.6	3.6	3.7	3.8	3.9
PATIENTS HOSPITALIZED (%)	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%
NUMBER OF PATIENTS HOSPITALIZED (MN)	1.9	1.9	2.0	2.0	2.1	2.1	2.1	2.2	2.2	2.3	2.3
PATIENTS IN EUROPEAN MARKETS (MN)	0.8	0.8	0.8	0.8	0.8	0.8	0.9	0.9	0.9	0.9	0.9
PENETRATION (%)	0%	0%	0%	0%	1%	1%	2%	1%	0%	0%	0%
NUMBER OF PATIENTS TREATED	0	0	0	0	4'109	8'383	12'825	9'811	2'002	408	83
COST OF THERAPY PER PATIENT (CHF)	1'260	1'260	1'260	1'260	1'260	1'260	1'260	1'260	1'260	1'260	1'260
SALES EUROPEAN MARKETS (CHF MN)	0	0	0	0	5	11	16	12	3	1	0
TRANSFER PRICE FOR CARDIOME (%)	35%	35%	40%	40%	45%	45%	50%	50%	55%	55%	55%
SALES EUROPEAN MARKETS (CHF MN)	**0**	**0**	**0**	**0**	**2**	**5**	**8**	**6**	**1**	**0**	**0**
PATIENTS IN DISTRIBUTOR REGIONS (MN)	1.1	1.2	1.2	1.2	1.2	1.3	1.3	1.3	1.3	1.4	1.4
PENETRATION (%)	0%	0%	0%	0%	0%	1%	1%	1%	0%	0%	0%
NUMBER OF PATIENTS TREATED	0	0	0	0	0	629	1'283	981	200	41	8
COST OF THERAPY PER PATIENT (CHF)	630	630	630	630	630	630	630	630	630	630	630
SALES DISTRIBUTOR REGIONS (CHF MN)	0	0	0	0	0	4	8	6	1	0	0
TRANSFER PRICE (%)	35%	35%	40%	40%	45%	45%	50%	50%	55%	55%	55%
SALES DISTRIBUTOR REGIONS (CHF MN)	**0**	**0**	**0**	**0**	**0**	**2**	**4**	**3**	**1**	**0**	**0**
SALES BOOKED BY BASILEA AT TRANSFER PRICE (CHF MN)	**0**	**0**	**0**	**0**	**2**	**7**	**12**	**9**	**2**	**0**	**0**
CHANGE (%)						181%	85%	-24%	-78%	-80%	-80%
UPFRONT & MILESTONE PAYMENTS (CHF MN)											
COGS (CHF MN)	0	0	0	0	-1	-2	-4	-3	-1	0	0
PROFIT BEFORE TAX (CHF MN)	**0**	**0**	**0**	**0**	**2**	**4**	**8**	**6**	**2**	**0**	**0**
TAXES (CHF MN)	0	0	0	0	0	0	0	0	0	0	0
PROFIT (CHF MN)	**0**	**0**	**0**	**0**	**2**	**4**	**8**	**6**	**1**	**0**	**0**

UNITED STATES - (PARTNER REQUIRED)	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
NUMBER OF PATIENTS (MN)	1.1	1.1	1.2	1.2	1.2	1.2	1.2	1.3	1.3	1.3	1.3
GROWTH (%)	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
PENETRATION (%)	0%	0%	0%	0%	1%	1%	2%	2%	3%	3%	4%
NUMBER OF PATIENTS TREATED	0	0	0	0	5'978	12'136	18'476	25'005	31'725	38'641	45'757
COST OF THERAPY PER PATIENT (CHF)	1'631	1'688	1'688	1'688	1'688	1'688	1'688	1'688	1'688	1'688	1'688
PARTNER SALES (CHF MN)	**0**	**0**	**0**	**0**	**10**	**20**	**31**	**42**	**54**	**65**	**77**
CHANGE (%)						103%	52%	35%	27%	22%	18%
ROYALTY (%)	0%	0%	0%	0%	20%	20%	20%	20%	20%	20%	20%
ROYALTIES (CHF MN)	0	0	0	0	2	4	6	8	11	13	15
UPFRONT & MILESTONE PAYMENTS (CHF MN)	0	0	0	30	20	0	0	0	0	0	0
R&D COSTS (CHF MN)	-15	-12	-1	0	0	0	0	0	0	0	0
PROFIT BEFORE TAX (USD MN)	**-15**	**-12**	**-1**	**30**	**22**	**4**	**6**	**8**	**11**	**13**	**15**
TAXES (CHF MN)	0	0	0	0	0	0	0	0	-2	-3	-3
PROFIT (CHF MN)	**-15**	**-12**	**-1**	**30**	**22**	**4**	**6**	**8**	**9**	**10**	**12**

	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
GLOBAL SALES (CHF MN)	**0**	**0**	**0**	**0**	**15**	**35**	**55**	**61**	**57**	**66**	**77**
CHANGE (%)						129%	58%	10%	-6%	15%	17%
GLOBAL PROFIT (CHF MN)	**-15**	**-12**	**-1**	**30**	**24**	**8**	**15**	**15**	**10**	**11**	**12**
CHANGE (%)	397%	-17%	-92%	-3100%	-21%	-64%	74%	1%	-35%	9%	16%

WACC (%)	7%	
NPV TOTAL PROFIT (CHF MN)	**100**	
NUMBER OF SHARES (MN)	10.9	
NPV PER SHARE (CHF)	**9**	
SUCCESS PROBABILITY	72.5%	(AVERAGE PHASE III (SAB) & FILING (ABSSI) SUCCESS RATE)
RISK ADJUSTED NPV PER SHARE (CHF)	**7**	

SENSITIVITY ANALYSIS

		WACC (%)						
	CHF/SHARE	5.5	6.0	6.5	7.0	7.5	8.0	8.5
	100%	10	10	10	9	9	9	8
	95%	10	9	9	9	8	8	8
	90%	9	9	9	8	8	8	8
	85%	9	8	8	8	8	7	7
SUCCESS PROBABILITY	80%	8	8	8	7	7	7	7
	75%	8	7	7	7	7	6	6
	72.5%	7	7	7	**7**	6	6	6
	70%	7	7	7	6	6	6	6
	65%	7	6	6	6	6	6	5

ESTIMATES AS OF 16 SEPTEMBER, 2019

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 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 NCE (new chemical entity) exclusivity granted for a newly approved product in the US. Zevtera received the designation for community-acquired bacterial pneumonia and acute bacterial skin and skin structure infections.

Phase: Zevtera is approved in thirteen European countries for the treatment of CABP and HABP, excluding VABP, in adults. In 2015 the drug was launched first in Germany, followed by Austria, Switzerland, the UK, France. Italy, and Spain. Pricing and reimbursement have been established in several core European countries. Basilea has made significant progress and expects revenue growth to start in the next few years.

Pathway: Basilea will have to conduct new pivotal phase III trials in the US to receive approval for treating lung, skin and bloodstream (bacteremia) bacterial infections. In April 2017 Basilea gained Special Protocol Assessment (SPA) for the cross-supportive phase III trial protocols for ABSSSI, which started in February 2018, and Staphylococcus aureus bacteremia (SAB – severe blood stream bacterial infections), expected to start in mid 2018. The BARDA agreement (up to USD 128 mn in funding) secured the necessary co-funding.

Patient: Zevtera is a well-tolerated broad-spectrum antibiotic that can be used empirically with high cure rates, with early improvement in HABP, particularly patients with MRSA, as well as in CABP, including high-risk patients. ICU stay was reduced by an average 3 days and hospital stays by 2 days in phase III clinical studies.

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 3 days and hospital stay by 2 days.

Partner: Cardiome now commercializes Zevtera in Europe 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 and the Nordics 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 up to 55% in the later years, except for CR Gosun where it receives 12% royalties and development and sales milestones.

Hospital Bacterial Infection Market

The USD 10+ bn hospital bacterial infection market is set for dynamic change.
On the positive side, market growth will be enhanced by:

1) Recent hospital antibiotics launches, including Allergan's Dalvance (acute skin infections) and Pfizer's/Allergan's Avycaz (complicated urinary tract & intra-abdominal infections), Merck & Co's Sivextro (acute skin infections) and Zerbaxa (complicated intra-abdominal & urinary tract infections) and The Medicines Company's Orbactiv (acute skin infections). Another 9 antibiotics are in phase III covering Gram-positive and -negative infections.
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 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 anti-MRSA hospital antibiotic market with global sales of USD 3.1 bn. The US is clearly the most important country for commercialization with 46% of global sales generated in the US, 18% in the EU-5, 15% in China, 4% in Japan and 17% in the ROW. For individual MRSA antibiotics their value share may reach up to 90% as seen for Cubicin prior to patent loss or for Allergan/Pfizer's Teflaro (ceftaroline).

HOSPITAL BACTERIAL INFECTIONS - KEY FACTS	
MARKET SIZE	USD 3.1 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 of the 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 in 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 growth of (bacteriostatic) the desired bacteria, but not the cells in a human body. Each type of antibiotic affects bacteria in different ways and are 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 external environment. Penicillin and vancomycin interact on 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 on this mechanism.
- **Synthesis of DNA and RNA:** By blocking 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 as a result of 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) 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 inadequate duration of therapy.

Cresemba (invasive mold infections: aspergillosis & mucormycosis)

Product Analysis

Cresemba peak sales of CHF 800+ mn - NPV of CHF 85 per share

We forecast global peak sales for Cresemba to amount to CHF 806 mn for treating invasive mold infections. Pfizer is now responsible for manufacturing and commercialization in Europe (excluding the Nordics), Russia, Turkey, Israel, China an Asia Pacific replacing the dedicated contract field force from Quintiles, which marketed Cresemba in the core European markets since Q1 2016. 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 11% to 22%. In the US, we assume Astellas to pay a tiered accumulated royalty rate rising from 15% to ~23% and sales milestones amounting to CHF 72 mn. In Europe, China and Asia Pacific, we assume Pfizer to pay sales royalties in the mid teen range and regulatory and sales milestones amounting to CHF 300 mn. Outside the Astellas and Pfizer regions (ROW), we assume distributor transfer prices ranging between 35-55% of the wholesale treatment price per patient (EUR 3,920), and declining COGS of 15-9%. Our NPV amounts to CHF 929 mn, or CHF 85 per share, using a WACC of 7% (for details see page 42).

Astellas, Pfizer and partners push Cresemba sales higher

Basilea's Cresemba (isavuconazole) is a novel intravenous and oral broad-spectrum antifungal for the treatment of 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 serious with high mortality rates up to 80% in some cases. Cresemba is now marketed in 33 countries globally including the US and the major European countries and is on track to reach the goal of 40 launched countries by the end of 2019. Basilea anticipates the number of launch countries to increase to 60 by the end of 2021. Basilea now has licensing and distribution agreements in place covering 115 countries globally, including the US, all EU member states, China and Japan. 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 (Middle East and North Africa – MENA region), Grupo Biotoscana (19 Latin American countries), Unimedic Pharma (the Nordics) and Avir Pharma (Canada). The existing partnerships for Cresemba and Zevtera include more than USD 175 mn in upfront payments and up to USD 1.1 bn potential regulatory and sales milestone payments, and royalties on sales. Basilea continues to seek partnerships for both products.

Global sales up 43% to USD ~170 mn in the 12-month period ending March 2019

In the 12-month period ending March 2019, the global in-market sales of Cresemba grew by 43% year-on-year to approximately USD 170 mn thanks to continued strong uptake in the US by partner Astellas and early launch countries in Europe by partner Pfizer. The strong uptake is expected to continue, thanks to growing contributions from new and recently launched markets, adding to the continued growth in the more established markets. In the US, Astellas reported Cresemba sales for January to June 2019 of USD 67 mn. For its fiscal

year 2019 (from April 2019 to March 2020) Astellas guides for USD 143 mn in Cresemba sales, reflecting and expected 20% growth year-on-year.

Astellas and Basilea have a long-lasting US collaboration on Cresemba

In 2010, Basilea announced a partnership agreement with Astellas for Cresemba. Astellas has an exclusive license for the United States. Operational oversight of the collaboration is controlled through a joint Steering Committee on the development and commercialization of Cresemba. Cresemba complements Astellas' antifungal portfolio, where Mycamine is only indicated for yeast infections and is available as an IV treatment only. Upon execution of the agreement Basilea received an upfront payment of CHF 75 mn. In 2014, Basilea received from Astellas a CHF 12 mn milestone payment on filing, followed by a CHF 30 mn milestone payment on US approval for treating invasive aspergillosis and mucormycosis in adults in March 2015, and was launched a month later. Basilea is still eligible for up to CHF 275 mn in sales milestone payments and double-digit tiered royalties on US sales starting at mid-teens and going up to mid-twenties, after reaching certain sales levels.

Pfizer agreement is a giant leap for the commercialization of Cresemba

The manufacturing and commercialization agreement announced in June 2017 with Pfizer for Cresemba for Europe (excluding the Nordics), Russia (including other CIS countries), Turkey and Israel, totaling more than 40 countries in Europe, is a giant leap for the rollout of Cresemba in Europe. The agreement was extended to China and Asia Pacific under the same terms in December 2017. The Pfizer agreement validates the sales potential of Cresemba, in our view. Pfizer is a global leader in anti-infectives with for instance its antifungal Vfend and antibiotic Zyvox. However, both are currently faced with increasing generic competition and microbial resistance. We expect Pfizer to aggressively market Cresemba to replace lost sales of its antifungal Vfend affected by generic competition, Cresemba was approved in the EU (all 28-member states) in October 2015 with the European rollout starting in 2016 in Germany, Italy, the UK, France, and Austria. In the core European markets Basilea used the same dedicated contract field force provided by Quintiles for selling its hospital antibiotic Zevtera. Since the start of 2018, Pfizer launched Cresemba in Switzerland, Ireland, Greece and the Netherlands, with more to come.

To date, Basilea received upfront payments from Pfizer totaling CHF ~78 mn (CHF 70 mn recognized over the period Basilea supplies Pfizer (maximum 5 year) and CHF 3 mn recognized in 2018, a USD 5 mn sales milestone recognized directly in FY 2019) and is eligible for additional regulatory and sales milestone payments of up to USD ~ 645 mn (recognized directly) and royalties on sales in the mid teen range. Given Pfizer's marketing muscle and strong presence in the antifungal field, now seeking to aggressively replace lost sales of its hospital antifungal Vfend facing generic competition in most European countries, and a continued strong US uptake by partner Astellas, we forecast global peak sales for Cresemba to amount to CHF 806 mn. Based on our detailed forecasts (see page 42) we believe Cresemba has become a profitable product franchise for Basilea thanks to the successful partnerships.

Asahi Kasei started Japanese registrational trial with potential launch in 2022

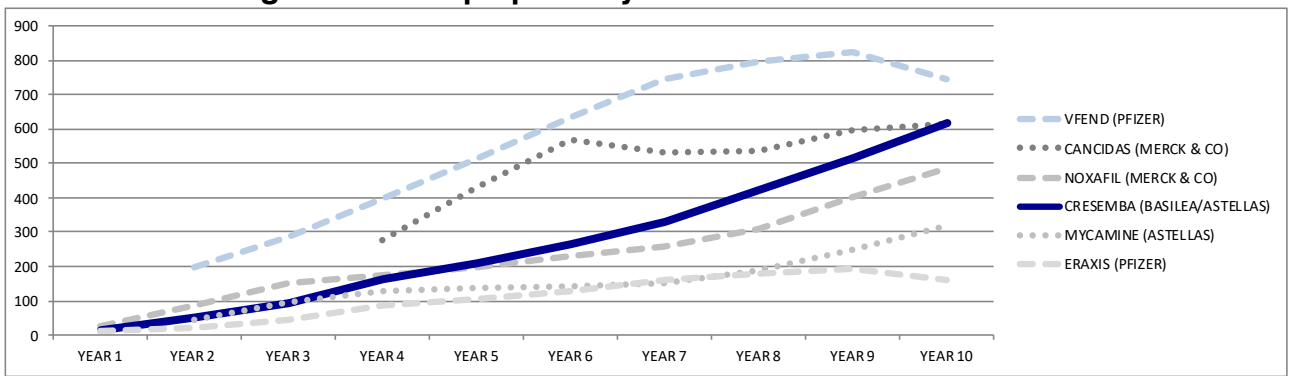
In 2016 Basilea entered into an agreement with Asahi Kasei Pharma to develop, register and commercialize Cresemba in Japan. Basilea received a CHF 7 mn upfront payment and is eligible for regulatory and commercial milestone payments of up to CHF 60 mn and double-digit tiered royalties on Japanese sales. In April 2018, Asahi Kasei started enrolment of the Japanese registrational phase III trial of Cresemba in deep-seated mycosis consisting

of invasive aspergillosis, chronic pulmonary aspergillosis, mucormycosis and cryptococcosis, with voriconazole as active comparator. Approximately 100 adult patients are expected to be enrolled. The trial is a part of an abbreviated development program to receive approval for Cresemba in Japan. Topline results are expected in 2021 with a Japanese launch expected around 2022. Japan currently represents about eight percent of the global market for invasive antifungals.

Cresemba on track to reach our peak sales of more than CHF 800 mn

After four years on the market, with staggered launches, first in the US in 2015, followed by the core European countries in 2016, Cresemba is off to a flying start (see graph below). Cresemba has outperformed other antifungal launches including Pfizer's Eraxis, and Astellas' Mycamine sales in their second year on the market. Pfizer's Vfend, 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, the first echinocandin antifungal on the market. Cresemba's sales ramp up is on track to meet our increased peak sales forecast of more than CHF 800 mn and has already surpassed the initial sales uptake of Merck & Co's Noxafil, which is used as prevention therapy for patients who are at a high risk of developing invasive mold and yeast infections, with 2017 sales of USD 738 mn (MAT Q1 2019).

Overview antifungal sales ramp up from year of launch



Source: Annual Reports, valuationLAB

Important ECIL guidelines recommend Cresemba as first-line treatment

The latest guideline issued by the European Conference on Infections in Leukemia (ECIL-6) recommends Cresemba for the first-line treatment (grade AI) of invasive aspergillosis in leukemia and hematopoietic stem cell transplant patients. The guideline states that 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 potentially important clinical role of Cresemba in the treatment of patients with these life-threatening infections, and should enhance further market penetration.

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 superficial 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 25-35% 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 improve outcomes.

Invasive fungal infections on the rise with frequent use of immunosuppressants

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

COMPETITIVE POSITIONING OF CRESEMBA

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

SOURCE: VALUATIONLAB, BASILEA

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 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 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 of HIV, solid organ and bone marrow transplant patients.

Three major drug classes - Pfizer's Vfend largest-selling antifungal

Cresemba targets a USD 3 bn 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)

Largest-selling drugs in 2017 include Pfizer's Vfend with USD 421 mn sales (down from USD 590 mn in 2016, impacted by generics), Merck & Co's Cancidas with USD 422 mn (from USD 558 mn in 2016, impacted by generics) and Noxafil USD 636 mn up 7%, Gilead's AmBisome USD 366 mn up 3%, and Astellas' Mycamine USD 353 mn, down 3%.

Cresemba has a competitive profile in particular its broad spectrum of activity
We believe Cresemba is competitively positioned, in particular due to its broad spectrum of activity that covers invasive mold (including mucormycosis) and yeast* infections, which 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 use has been hampered by infusion site reactions and toxicities. Candins such as Cancidas is 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 for 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 (see "SECURE" results below). 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.

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 (for more details see "ACTIVE" trial results on page 19 and 20).

Cresemba's three key points of differentiation:

1) **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%). We believe physicians will be inclined to use Cresemba more empirically because of its broad coverage and the risk of not covering mucormycosis. A delay 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. Overall, 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 less peaks and troughs as with Vfend. This could also be one of the reasons why Vfend leads to more side effects.

Additionally, 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.

Approval in mold infections, uncertainty in yeast infections

The phase III program with Cresemba to investigate its role in treating invasive fungal infections included three trials:

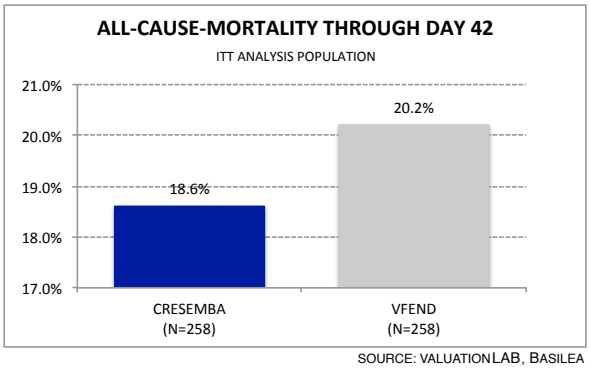
1. **"SECURE"** a global double-blind randomized phase III trial, designed to evaluate the safety and efficacy of once-daily Cresemba versus Pfizer's twice-daily Vfend (voriconazole) in the primary treatment of invasive fungal disease caused by Aspergillus species or other filamentous fungi: Primary & 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, secondary endpoints met

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

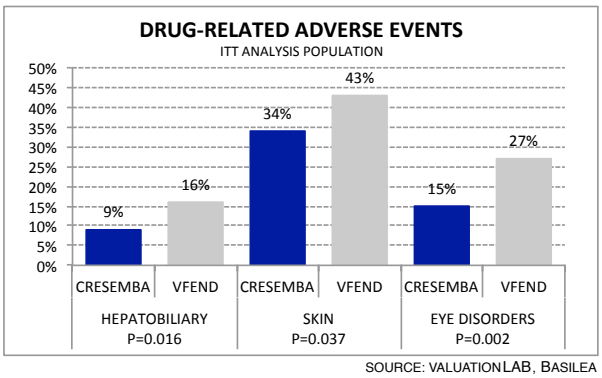
"SECURE" was a randomized, double blind, non-inferiority active controlled trial, which evaluated the safety and efficacy of Cresemba versus Pfizer's Vfend (voriconazole) for primary treatment of invasive fungal disease caused by Aspergillus species or other filamentous fungi. Patients randomized to 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. Mean treatment duration was 47 days for both treatment groups, of which 8 to 9 days was 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: intend-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 of -8.0% to 5.9%. Similar results were seen in patients with proven or probable invasive aspergillosis confirmed by serology, culture or histology.



SOURCE: VALUATIONLAB, BASILEA



SOURCE: VALUATIONLAB, BASILEA

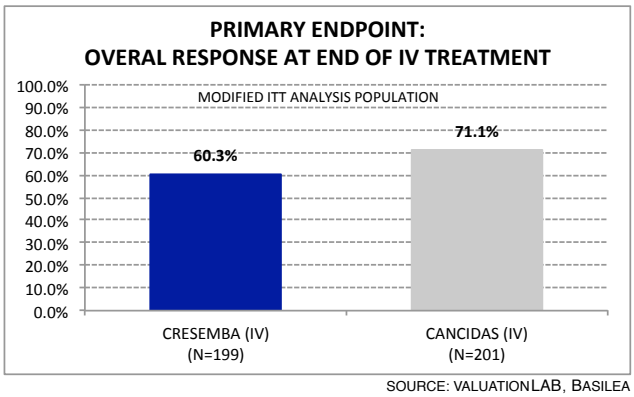
Favorable safety profile with fewer drug-related adverse events in several organs
The overall safety profile of Cresemba showed similar rates of mortality and adverse events as with Vfend in the overall ITT population. In patients with invasive aspergillosis there were significantly fewer drug-related 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 (rare mold infection with 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. 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.

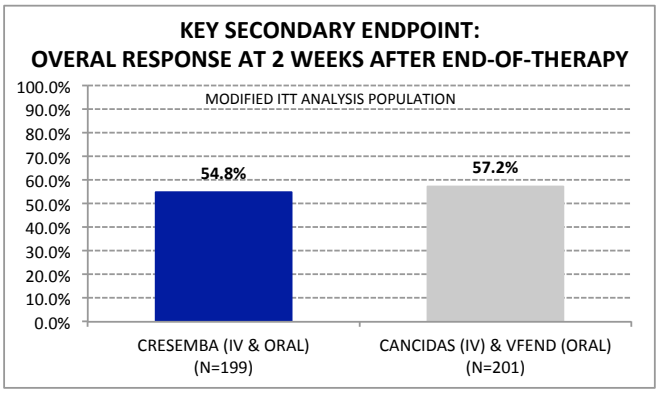
The results provided evidence that Cresemba is effective for the treatment of mucormycosis, in light of the natural history of untreated mucormycosis:

- 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 "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 – still potential role as oral step-down?
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 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 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 end of treatment was the key secondary endpoint of the study. In addition, the secondary endpoint of all-cause mortality was comparable at 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.

Potential role as oral step-down therapy under investigation
Basilea is currently reviewing the trial results in more detail for a comprehensive understanding of the findings. A specific focus will be on secondary endpoint data and subgroup analyses to evaluate potential options, and to explore with key opinion leaders the potential role of Cresemba for treating candidemia or invasive candidiasis, such as the potential use as an oral step-down therapy.

While the primary endpoint at the end of IV therapy in “ACTIVE” was not met, key secondary endpoints were achieved with a number of considerations:

- “ACTIVE” supports the current treatment recommendation to use a candin as first-line treatment in invasive candidiasis; the limitation of candins is their absence of an oral formulation, which limits long-term or outpatient treatment.
- The study confirmed prior evidence that candins and azoles are effective in the overall treatment of invasive candidiasis but at different response rates for IV treatment.
- The key secondary endpoint where all-cause-mortality rates 2 weeks after end of therapy were comparable between the two treatment groups, potentially supports the use of Cresemba as a second-line treatment or oral step-down treatment in invasive Candida infections.

There are potential advantages of Cresemba compared to the azoles currently used in the oral step-down setting (fluconazole or Vfend): Cresemba has in-vitro activity against fluconazole-resistant Candida. Compared to Vfend Cresemba has a favorable side-effect profile, a predictable pharmacokinetic and pharmacodynamic profile, is once-daily compared to twice-daily, and has a favorable drug-drug interaction profile especially regarding immunosuppressants.

Cresemba forecasts based on invasive mold infections only

We have based our sales forecasts for Cresemba exclusively on invasive mold infections including aspergillosis and mucormycosis in adults. We exclude any sales in yeast infections, although these could occur should Cresemba be included in treatment guidelines as an oral step-down therapy following Cancidas treatment. However, it is too soon to speculate whether this will occur based on the topline results of “ACTIVE”.

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

1. **European markets** (now commercialized by Pfizer, replacing the dedicated contract field force from Quintiles)
2. **China** (commercialized by Pfizer)
3. **ROW** (distributors)
4. **US** (Astellas Pharmaceuticals)
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 285 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 to additional regulatory and commercialization milestones up to USD ~650 mn from Pfizer. In Japan, Basilea will receive double-digit tiered royalties on sales from Asahi Kasei and is eligible to up to CHF 60 mn in regulatory and sales milestones.

Europe: We believe peak sales in Europe could amount to around CHF 217 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 22% and 10-years orphan drug and 2 years pediatric market exclusivity until 2027.
China: We have included forecasts for China and Asia Pacific to reflect the recent extension of the Pfizer agreement in December 2017 to this region. We forecast peak sales conservatively to amount to CHF ~120 mn.
ROW: Peak sales in the ROW are expected to amount to around CHF 178 mn. We assume Basilea sells Cresemba to its distributors at a discounted transfer price. The distributor makes his profit off the difference between the wholesale price and discounted transfer price. 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 have raised our peak sales forecast for Cresemba to approximately CHF 260 mn, reflecting the good uptake in H1 2019, 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 starting at ~15% and gradually peaking at ~22% (this is the average royalty rate over the tiered values). We have conservatively accounted for a total of CHF 72 mn sales milestone payments.
Japan: We expect peak sales in Japan to amount to around CHF 80 mn with first sales starting 2022 and similar pricing as in the US. We conservatively account for a total of CHF 39 mn regulatory and sales milestone payments.

Based on global peak sales amounting to CHF 806 mn and a WACC of 7%, we derive an NPV of CHF 929 mn or CHF 85 per share for Cresemba in invasive mold infections.

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 275 MN MILESTONES, D.D. TIERED ROYALTIES; PFIZER (EUROPE, CHINA, ASIA-PACIFIC): UP TO USD 645 MN MILESTONES, MID-TEEN ROYALTIES

REVENUE MODEL

EUROPE	**2018E**	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**
NUMBER OF PATIENTS	337'948	343'017	348'162	353'385	358'685	364'066	369'527	375'070	380'696	386'406	392'202
GROWTH (%)	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
PATIENTS IN BASILEA CORE EU MARKETS	135'179	137'207	139'265	141'354	143'474	145'626	147'811	150'028	152'278	154'562	156'881
PENETRATION (%)	4%	6%	8%	11%	13%	16%	18%	20%	22%	20%	8%
NUMBER OF PATIENTS TREATED	5'813	8'781	11'698	15'408	19'226	22'791	26'458	30'231	34'186	31'229	12'679
COST OF THERAPY PER PATIENT (CHF)	6'415	6'354	6'354	6'354	6'354	6'354	6'354	6'354	6'354	6'354	6'354
EUROPE SALES (CHF MN)	**37**	**56**	**74**	**98**	**122**	**145**	**168**	**192**	**217**	**198**	**81**
CHINA, ASIA PACIFIC SALES (PFIZER) (CHF MN)						**10**	**32**	**54**	**76**	**98**	**120**
TOTAL SALES EUROPE, CHINA, ASIA PACIFIC (PFIZER) (CHF MN)	**37**	**56**	**74**	**98**	**122**	**155**	**200**	**246**	**293**	**296**	**201**
ROYALTY (%)	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
ROYALTIES (15%) (CHF MN)	6	8	11	15	18	23	30	37	44	44	30
UPFRONT & MILESTONE PAYMENTS (CHF MN)	27	33	25	20	0	38	30	43	40	53	18
COGS (%)	49%	35%	15%	0%	0%	0%	0%	0%	0%	0%	0%
COGS (CHF MN)	-18	-20	-11	0	0	0	0	0	0	0	0
SG&A (CHF MN)	-2	-2	-2	-2	-2	-2	-2	-2	-1	-1	0
OPERATING EXPENSES (CHF MN)	-20	-21	-13	-2	-2	-2	-2	-2	-1	-1	0
PROFIT BEFORE TAX (CHF MN)	**13**	**20**	**23**	**33**	**16**	**60**	**58**	**78**	**83**	**97**	**48**
TAX RATE (%)	0%	0%	0%	0%	0%	0%	0%	0%	20%	20%	20%
TAXES (CHF MN)	0	0	0	0	0	0	0	0	-17	-19	-10
PROFIT (CHF MN)	**13**	**20**	**23**	**33**	**16**	**60**	**58**	**78**	**66**	**78**	**38**

REST OF WORLD (DISTRIBUTORS)	**2018E**	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**
PATIENTS IN DISTRIBUTOR REGIONS	202'769	205'810	208'897	212'031	215'211	218'439	221'716	225'042	228'417	231'844	235'321
PENETRATION (%)	1%	2%	3%	5%	8%	10%	13%	15%	18%	16%	6%
NUMBER OF PATIENTS TREATED	1'090	3'164	6'345	10'681	16'222	21'926	27'798	33'841	40'059	36'594	14'857
COST OF THERAPY PER PATIENT (CHF)	4'490	4'448	4'448	4'448	4'448	4'448	4'448	4'448	4'448	4'448	4'448
SALES DISTRIBUTOR REGIONS (CHF MN)	5	14	28	48	72	98	124	151	178	163	66
TRANSFER PRICE (%)	35%	35%	40%	40%	45%	45%	50%	50%	55%	55%	55%
BASILEA SALES DISTRIBUTOR REGIONS (CHF MN)	**2**	**5**	**11**	**19**	**32**	**44**	**62**	**75**	**98**	**90**	**36**
COGS (CHF MN)	-1	-2	-3	-6	-9	-12	-15	-18	-21	-20	-8
PROFIT BEFORE TAX (CHF MN)	**1**	**3**	**8**	**13**	**24**	**32**	**47**	**57**	**77**	**70**	**28**
TAXES (CHF MN)	0	0	0	0	0	0	0	0	-15	-14	-6
PROFIT (CHF MN)	**1**	**3**	**8**	**13**	**24**	**32**	**47**	**57**	**61**	**56**	**23**

UNITED STATES (ASTELLAS)	**2018E**	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**
NUMBER OF PATIENTS	225'299	228'678	232'108	235'590	239'124	242'710	246'351	250'046	253'797	257'604	261'468
PENETRATION (%)	8%	9%	11%	12%	13%	14%	15%	16%	16%	13%	3%
NUMBER OF PATIENTS TREATED	18'024	21'267	24'603	28'035	31'564	34'465	37'445	39'257	39'846	32'355	6'568
COST OF THERAPY PER PATIENT (CHF)	6'388	6'610	6'610	6'610	6'610	6'610	6'610	6'610	6'610	6'610	6'610
SALES (CHF MN)	**115**	**141**	**163**	**185**	**209**	**228**	**247**	**259**	**263**	**214**	**43**
AVERAGE ROYALTY (%)	18%	19%	20%	21%	21%	21%	22%	22%	22%	21%	16%
ROYALTIES (CHF MN)	21	27	33	38	44	49	54	57	58	45	7
UPFRONT & MILESTONE PAYMENTS (CHF MN)	10	14			21		25		12		
PROFIT BEFORE TAX (CHF MN)	**31**	**41**	**33**	**38**	**65**	**49**	**79**	**57**	**70**	**45**	**7**
TAX RATE (%)	0%	0%	0%	0%	0%	0%	0%	0%	20%	20%	20%
TAXES (CHF MN)	0	0	0	0	0	0	0	0	-14	-9	-1
PROFIT (CHF MN)	**31**	**41**	**33**	**38**	**65**	**49**	**79**	**57**	**56**	**36**	**6**

JAPAN (ASAHI KASEI)	**2018E**	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**
NUMBER OF PATIENTS	90'137	91'940	93'779	95'655	97'568	99'519	101'509	103'540	105'610	107'723	109'877
PENETRATION	0%	0%	0%	0%	3%	5%	7%	9%	10%	11%	3%
NUMBER OF PATIENTS TREATED	0	0	0	0	3'122	5'374	7'512	9'422	10'772	12'173	3'725
COST OF THERAPY PER PATIENT (CHF)	6'388	6'610	6'610	6'610	6'610	6'610	6'610	6'610	6'610	6'610	6'610
SALES (CHF MN)	**0**	**0**	**0**	**0**	**21**	**36**	**50**	**62**	**71**	**80**	**25**
ROYALTIES (~12%) (CHF MN)	0	0	0	0	2	4	6	7	9	10	3
UPFRONT & MILESTONE PAYMENTS (CHF MN)	1	1	1	6	7	2	3	4	5	6	2
PROFIT BEFORE TAX (CHF MN)	**1**	**1**	**1**	**6**	**10**	**7**	**9**	**12**	**14**	**15**	**5**
TAXES (CHF MN)	0	0	0	0	0	0	0	0	-3	-3	-1
PROFIT (CHF MN)	**1**	**1**	**1**	**6**	**10**	**7**	**9**	**12**	**11**	**12**	**4**

	2018E	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**
GLOBAL SALES (CHF MN)	**157**	**210**	**265**	**331**	**424**	**516**	**621**	**718**	**806**	**754**	**335**
CHANGE (%)	69%	34%	26%	25%	28%	22%	20%	16%	12%	-7%	-56%
GLOBAL PROFIT (CHF MN)	**46**	**66**	**64**	**91**	**115**	**147**	**193**	**204**	**194**	**182**	**70**
CHANGE (%)	532%	43%	-2%	41%	27%	28%	31%	6%	-5%	-6%	-61%

WACC (%)	7%
NPV TOTAL PROFIT (CHF MN)	**929**
NUMBER OF SHARES (MN)	10.9
RISK ADJUSTED NPV PER SHARE (CHF)	**85**

SENSITIVITY ANALYSIS

		WACC (%)						
	CHF/SHARE	5.5	6.0	6.5	7.0	7.5	8.0	8.5
	950	109	106	78	101	99	97	95
	900	103	101	98	96	94	92	90
	850	98	95	93	91	89	87	85
PEAK SALES (CHF MN)	800	92	90	87	**85**	83	82	80
	750	86	84	82	80	78	76	75
	700	80	78	77	75	73	71	70
	650	75	73	71	69	68	66	65

ESTIMATES AS OF 16 SEPTEMBER, 2019

SOURCE: VALUATIONLAB ESTIMATES

Unique Selling Point

Cresemba has broad-spectrum of activity covering invasive mold (aspergillus & mucorales) and yeast (Candida) infections, with a favorable safety profile and a predictable drug exposure and can be given to patients with impaired kidneys. The drug can be given intravenously in a hospital setting, and once the patient has recovered sufficiently, can be taken at home orally.

7P's Analysis

Patent: Cresemba enjoys 12 years market exclusivity in the US consisting of 7 years orphan drug exclusivity and 5 years QIDP exclusivity. As the drug was approved in March 2015, US exclusivity lasts until March 2027. In the EU Cresemba will enjoy 10 years 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. Basilea is reviewing the mixed data from “ACTIVE” and is in discussions with key opinion leaders what the role of Cresemba could be in treating invasive yeast infections. There could still be potential as a second-line or oral step-down treatment following initial IV candin treatment, in our view (excluded in our forecasts).

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 and 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 a good safety and tolerability profile, including patients with kidney problems (32-40% of patients). Moreover, Cresemba has less drug interactions, and can be given together with many other commonly used drugs in this fragile population.

Payer: “Treating right the first time” 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 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 peaking at ~23%. In Europe, China, Asia Pacific Pfizer is now responsible for commercialization. Basilea is eligible up to USD ~645 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 up to CHF 60 mn milestones. Outside these regions, there are distribution agreements for Latin America, the Nordics, Canada and the Middle East and North Africa. We assume distributor transfer prices to start at 35% of the wholesale price increasing to 55% as Cresemba sales mature.

Invasive Fungal Infections Market

The global antifungal 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. Global sales of best-in-class antifungals amounted to USD 3 bn (MAT Q1 2019). Largest-selling hospital antifungals include Merck & Co's Noxafil (posaconazole) with sales of USD 738 mn (25% market share), followed by Pfizer's Vfend (voriconazole) at USD 688 mn (23%), Merck & Co's Cancidas (caspofungin) at USD 461 mn (15%), Gilead's liposomal formulation of amphotericin B, branded AmBisome at USD 434 mn (15%), Astellas' Mycamine (micafungin) at USD 332 mn (11%), Basilea's Cresemba (isavuconazole) at USD 168 mn (6%), and Pfizer's Eraxis (anidulafungin) at USD 158 mn (5%).

It is estimated that the EU Top-5 countries accounted for 35% of the invasive antifungal market of new azoles and candins in 2015, followed by ROW (34%), US (22%), and Japan (9%), respectively. The US usually generates a higher proportion of sales with its generally higher treatment prices. This is not the case with invasive antifungals, where there are limited branded treatment options with relatively high differentiation, and few effective generics. This leads to high treatment prices worldwide. Nevertheless, in the next few years we expect dynamic change of the market caused by: 1) patent expirations of some key drugs including Vfend, AmBisome and Cancidas; 2) new market entrants such as Basilea's azole Cresemba; and 3) increasing resistance to current treatments.

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 in 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 ageing 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. **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 25-38%
2. **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)

Increasing rate of invasive fungal infections adding to total treatment costs

These high mortality rates compare to that of severe sepis 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 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 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 start treatment early and with the right treatment choice.

- Patients at risk of invasive aspergillosis comprise of 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 tolerabily and safety profile.

Derazantinib (intrahepatic cholangiocarcinoma - iCCA)

Product Analysis

Intrahepatic cholangiocarcinoma (bile duct cancer): rNPV of CHF 3/share: we forecast peak sales for derazantinib in treating patients with intrahepatic cholangiocarcinoma (iCCA) to amount to CHF 100+ mn with first launches expected in 2023, US and EU patent expiry in 2034/2035 (based on anticipated patent term extensions), an annual treatment cost per patient (~7 months treatment) of USD 100,000 (US) and CHF 70,000 (EU/ROW), a market penetration peaking at ~38-45% and CHF 59 mn development costs. We assume Basilea will seek development and commercialization partners on positive phase III results in iCCA in return for a net royalty rate of between 15-19% and CHF 25 mn net upfront and milestone payments (after paying ArQule staggered single to double digit royalties and sales milestones). We calculate a rNPV of CHF 56 mn or CHF 3 per share for derazantinib in iCCA with a 50% (registrational phase II trial) success rate and a WACC of 7% (for details see page 50)

NOTE: iCCA is a fast-to-market rare disease indication for derazantinib. Considerably more upside could come from larger cancer indications, such as lung (#2 cancer with ~220,000 cases per year in the US), breast (#3 cancer with ~195,000 US cases per year) and bladder cancer (#6 cancer with ~71,000 US cases per year). In August 2019, Basilea started a POC trial of derazantinib alone or in combination with Roche's PD-L1 checkpoint inhibitor Tecentriq (atezolizumab) in patients with advanced urothelial cancer. We exclude these cancer indications in our forecasts until proof-of-concept has been established.

iCCA an important steppingstone to large cancer indications

Basilea licensed the worldwide rights (excluding China, Hong Kong, Macau and Taiwan) for derazantinib (ARQ 087) from ArQule in April 2018. Derazantinib is a novel oral panFGFR (fibroblast growth factor receptor) inhibitor that targets various solid tumors, including intrahepatic cholangiocarcinoma, bladder, breast, gastric and lung cancer, where FGFR alterations range between 5-30%. In 2017, ArQule started a registrational phase II trial in intrahepatic cholangiocarcinoma (iCCA) – a form of bile duct cancer, which is rare with a poor prognosis if inoperable due to a lack of effective treatments. This is a small, but fast-to-market indication. Orphan drug designation (ODD) was granted for iCCA in the EU and US. ODD provides 7-years (US) and 10-years (EU) orphan drug marketing exclusivity upon approval. ArQule received a USD 10 mn upfront payment from Basilea and is eligible to regulatory and sales milestones of up to USD 326 mn as well as staggered single to double-digit sales royalties.

We forecast peak sales of derazantinib of CHF 100+ mn in iCCA alone. Basilea expects to run a phase III trial to achieve both EU and US approval, which may complete in 2022. We assume Basilea seeks a commercialization partner upon successful completion of phase III development in iCCA or potentially sooner on demonstrable proof-of-concept in large cancer indications.

First major cancer indication for derazantinib in combination with Roche's Tecentriq

In January 2019, Basilea entered into a clinical supply agreement with Roche to explore a combination of Roche's Tecentriq (atezolizumab) a PD-L1 checkpoint inhibitor in patients with advanced urothelial cancer. In August 2019, Basilea started a global, open label,

biomarker-driven, multi-cohort phase I/II proof-of-concept trial to assess the safety, tolerability and efficacy of derazantinib alone and in combination with Tecentriq in patients with advanced urothelial cancer and confirmed FGFR gene aberrations. Roche will provide Tecentriq for free. First interim results may be available 12-18 months after start of recruitment with the different cohorts likely to be tracking on slightly different timelines. Completion may be expected around 12 months after the interim results for each cohort. Additional collaborations and/or trials in other large cancer indications where FGFR alterations play a role are expected in the future.

Derazantinib is a potent panFGFR inhibitor with promise in a number of cancers

Derazantinib is an oral drug designed to selectively inhibit the FGFR (fibroblast growth factor receptor) family of kinases with demonstrated activity in FGFR2 genetic alterations, including fusions. Fibroblast growth factors and their receptors tightly regulate key cellular behaviors, such as proliferation, cell differentiation, cell migration, cell survival and angiogenesis, which all interplay in tumor formation. FGFR dysregulation has been identified as a driver in a number of cancers, including iCCA, bladder, endometrial, breast, gastric, lung and ovarian. Current scientific literature suggests FGFR dysregulation exists in anywhere from 5% to 30% of these cancers. The FGFR family consists of four genes encoding tyrosine kinase receptors (FGFR1, FGFR2, FGFR3, and FGFR4). Derazantinib is a potent, oral panFGFR inhibitor that shows strong anti-proliferative activity in cell lines harboring FGFR2 alterations. Derazantinib has demonstrated in vivo inhibition of tumor growth and downstream signaling in tumors whose growth is driven by FGFR targets.

Key characteristics of derazantinib:

- Oral drug that potently inhibits FGFR1, 2, 3 and 4 with demonstrated clinical activity
- Positive response rate observed in biomarker-defined iCCA population with FGFR2 fusions
- Potential for best-in-class safety profile and low discontinuation rate
- Consistent drug exposure with once-a-day dosing regimen
- Drug profile allows for combination therapy (e.g. with VEGFR's such as Roche's Tarceva and Bayer's Nexavar)

iCCA is rare form of bile duct cancer with a poor prognosis if inoperable

Cholangiocarcinoma, also known as bile duct cancer, is a form of cancer that is composed of mutated epithelial cells (or cells showing characteristics of epithelial differentiation) that originate in the bile ducts, which drain bile from the liver into the small intestines. Cholangiocarcinoma can affect any area of the bile ducts, either within or outside the liver. Tumors occurring in the bile ducts within the liver are referred to as intrahepatic, those occurring in the ducts outside the liver are extrahepatic. Intrahepatic cholangiocarcinoma (iCCA) is a rare form of bile duct cancer that originates from the intrahepatic biliary ductal system and forms an intrahepatic mass with an annual incidence rate of 1-2 cases per 100,000 in the Western world (10 per 100,000 in China and 71 per 100,000 in Thailand) that has been rising in the past few decades. It is the second most common malignancy arising from the liver. iCCA is considered to be an incurable and rapidly lethal cancer unless both the primary tumor and any metastases can be fully removed by surgery (resection). No potentially curative treatment exists except surgery, but most patients have advanced stage disease at presentation and are inoperable at the time of diagnosis. Most patients have no identifiable risk factors. Only a minority of patients (15%) present with resectable disease, with a median survival of less than 3 years. The resection rate is low because at the time of diagnosis this disease is frequently beyond the limits of surgical therapy. Patients with

cholangiocarcinoma are generally managed - though not cured – with chemotherapy (e.g. fluoropyrimidine or gemcitabine-based), radiation therapy, and other palliative care measures.

FGFR2 fusion in 10-20% of iCCA patients that can be targeted with derazantinib
Scientific studies suggest that 10% to 20% of the iCCA population has a FGFR2 fusion. Molecular characterization of iCCA by diagnostic tests such as next-generation sequencing (NGS) and fluorescence in situ hybridization (FISH) have enabled identification of genetic alterations that can potentially be treated by targeted therapies like derazantinib that inhibits FGFR2 alteration. Such a diagnostic test known as a companion diagnostic may need to be developed and cleared or approved in parallel with derazantinib in order to identify patients who are likely to respond to therapy.

Registrational phase II biomarker-driven trial in iCCA started in 2017
Given the high unmet need, iCCA was selected as the first indication for derazantinib in a registrational phase II biomarker-driven trial designed with FDA and EMA feedback, which started in 2017. The target population consists of second line iCCA patients who are inoperable and are FGFR2 fusion positive or advanced iCCA patients. The trial is an open-label single arm trial that is response-rate driven in currently 16 sites across the US (8), Canada (2) and Italy (6) and is estimated to enroll approximately 100 patients. The key objectives are to demonstrate efficacy of derazantinib as measured by objective response rate (primary endpoint – time frame up to approximately 32 weeks), progression free survival, overall survival and duration of response, and safety as assessed by adverse events.

Positive interim results reported in January 2019 – Topline results due end 2020
In January 2019, Basilea reported promising interim results of the ongoing registrational open-label phase II trial of derazantinib in patients with FGFR2 gene fusion-expressing iCCA with confirmed safety and tolerability observed in previous clinical trials. The interim analysis was conducted after 42 patients had been enrolled, with a subset of 29 evaluable patients who had at least one post-baseline imaging assessment. The ORR (objective response rate) was 21% with six confirmed partial responses (three times the rate observed with chemotherapy). The DCR (disease control rate), reflecting the proportion of patients with a partial response or stable disease was 83%. Several patients are still on treatment improving the overall duration of treatment. The prognosis for patients with advanced disease is poor with a median survival of less than one year. There is no proven effective treatment for patients who progress on first-line therapy, which is currently chemotherapy in combination with gemcitabine and platinum-derived agents.

The ongoing registrational open label registrational trial is expected to enroll up to 100 patients with inoperable or advanced iCCA expressing FGFR2 gene fusions. An additional cohort of iCCA patients whose tumors express FGFR gene mutations is expected to enroll approximately 43 patients. Final data is expected upon completion of the trial in mid-2020.

If the trial is successful, derazantinib could receive accelerated approval in the US with first launches to occur in 2021(conservatively not in our forecasts). Basilea expects to run a phase III trial to achieve both EU and US approval with first launches to potentially occur around 2023. Upon approval, a companion diagnostic may be required by the FDA and EMA to target FGFR2 fusion positive iCCA patients.

We forecast peak sales of CHF 100+ mn for derazantinib in iCCA alone

We have based our sales forecasts for derazantinib only on its first, fast to market, and orphan drug indication, iCCA. Considerably larger peak sales forecasts and upside could come from large cancer indications such as lung cancer (#2 cancer; ~13% FGFR alterations in squamous cell lung cancer), breast cancer (#3 cancer; ~18% FGFR alterations) and bladder cancer (#6 cancer; ~32% FGFR alterations).

In our detailed forecasts for derazantinib in iCCA, we assume Basilea will seek commercialization partners and have accounted for two distinctive regions:

1. **US:** we believe peak sales could amount to CHF 56 mn assuming an annual treatment price per patient of USD 100,000 (7-8 months treatment) assuming first launches in 2023 (priority review) with a market peak penetration reaching 45% and patent expiry in 2034/2035 (including patent term extension). We assume Basilea receives net royalties of between 19% and 15% of sales and net milestone payments of CHF 9 mn (after paying ArQule staggered single to double digit royalties on sales and sales milestones)
2. **Europe/ROW:** we forecast peak sales to amount to CHF 61 mn assuming an annual treatment price per patient of CHF 70,000 (7-8 months treatment) assuming first launches in 2023 with a market penetration reaching 38% and patent expiry in 2034 (including patent term extension under SPC). We assume Basilea receives the same net royalty rates as in the US and net milestones of CHF 15 mn (after payments to ArQule).

Forecasts & Sensitivity Analysis

DERAZANTINIB - FINANCIAL FORECASTS FOR INTRAHEPATIC CHOLANGIOCARCINOMA

INDICATION	TREATMENT OF FGFR2 GENE FUSION POSITIVE INOPERABLE OR ADVANCED INTRAHEPATIC CHOLANGIOCARCINOMA (FORM OF BILE DUCT CANCER)
DOSAGE	ONCE-DAILY 300 MG ORAL CAPSULE
PRICE	WE ASSUME A TREATMENT COST PER PATIENT OF USD 100,000 (US) AND CHF 70,000 (EU/ROW) BASED ON A 7-8 MONTHS TREATMENT DURATION
STANDARD OF CARE	SURGICAL RESECTION, SYSTEMIC CHEMOTHERAPY (PREOPERATIVE, ADJUVANT, PALLIATIVE, HEPATIC ARTERIAL INFUSION)
UNIQUE SELLING POINT	POTENTIALLY ONE OF THE FIRST TARGETED THERAPIES TO TREAT ICCA PATIENTS; POTENTIAL IN LARGER INDICATIONS SUCH AS BLADDER CANCER

7Ps ANALYSIS

PATENT	US: EXPIRY (DEC 2029/JAN 2031) & 5-YEARS EXTENSION, 7-YEARS ODD EXCLUSIVITY; EU: EXPIRY (DEC 2029) & 5-YEARS SPC EXTENSION, 10-YEARS ODD
PHASE	REGISTRATIONAL PHASE II TRIAL, POTENTIAL US ACCELERATED APPROVAL (2021E); PHASE III TRIAL LIKELY FOR US/EU APPROVAL (2023E); PHASE I/II UROTHELIAL TRIAL (AUG 2019)
PATHWAY	ORPHAN DRUG DESIGNATION GRANTED IN THE US AND EU; ELIGIBLE FOR PRIORITY REVIEW
PATIENT	POTENTIAL TO IMPROVE SURVIVAL AND QUALITY OF LIFE IN THIS PATIENT POPULATION WITH A POOR PROGNOSIS
PHYSICIAN	NEW TARGETED THERAPY WITH POTENTIAL TO IMPROVE SURVIVAL IN COMBINATION WITH CURRENT TREATMENT REGIMENS
PAYER	LOWER OVERALL TREATMENT COSTS DUE TO AN IMPROVEMENT IN SURVIVAL, LESS HOSPITALIZATION AND OTHER TREATMENT COSTS
PARTNER	GLOBAL RIGHTS (EXCL. CHINA) ACQUIRED FROM ARQULE IN APR 2018; WE ASSUME BASILEA SEEKS COMMERCIALIZATION PARTNERS AFTER PHASE III

REVENUE MODEL

EUROPE / REST OF WORLD	**2018E**	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**
NUMBER OF PATIENTS (INCIDENCE 1-2 PER 100,000)	11,668	11,902	12,140	12,383	12,630	12,883	13,141	13,403	13,671	13,945	14,224
GROWTH (%)	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
FGFR FUSIONS (%)	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
ICCA PATIENTS WITH FGFR FUSIONS	1,750	1,785	1,821	1,857	1,895	1,932	1,971	2,010	2,051	2,092	2,134
PENETRATION (%)	0%	0%	0%	0%	0%	8%	18%	26%	32%	36%	37%
NUMBER OF TREATED PATIENTS	0	0	0	0	0	155	355	523	656	753	789
COST OF THERAPY PER PATIENT (CHF)	70,000	70,000	70,000	70,000	70,000	70,000	70,000	70,000	70,000	70,000	70,000
SALES (CHF MN)	**0**	**0**	**0**	**0**	**0**	**11**	**25**	**37**	**46**	**53**	**55**
CHANGE (%)							130%	47%	26%	15%	5%
NET ROYALTY RATE (%)						19%	19%	19%	17%	17%	17%
NET ROYALTIES (CHF MN)	0	0	0	0	0	2	5	7	8	9	9
NET UPFRONT & MILESTONE PAYMENTS (CHF MN)	0	0	0	0	0	5	0	0	0	5	0
R&D COSTS (CHF MN)	0	0	0	0	0	0	0	0	0	0	0
PROFIT BEFORE TAX (CHF MN)	**0**	**0**	**0**	**0**	**0**	**7**	**5**	**7**	**8**	**14**	**9**
TAX RATE (%)	0%	0%	0%	0%	0%	0%	0%	0%	20%	20%	20%
TAXES (CHF MN)	0	0	0	0	0	0	0	0	-2	-3	-2
PROFIT (CHF MN)	**0**	**0**	**0**	**0**	**0**	**7**	**5**	**7**	**6**	**11**	**8**

UNITED STATES	**2018E**	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**
NUMBER OF PATIENTS (INCIDENCE 1-2 PER 100,000)	6,489	6,619	6,751	6,886	7,024	7,164	7,307	7,454	7,603	7,755	7,910
GROWTH (%)	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
FGFR FUSIONS (%)	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
ICCA PATIENTS WITH FGFR FUSIONS	973	993	1,013	1,033	1,054	1,075	1,096	1,118	1,140	1,163	1,186
PENETRATION (%)	0%	0%	0%	0%	0%	15%	23%	30%	36%	40%	43%
NUMBER OF TREATED PATIENTS	0	0	0	0	0	161	252	335	411	465	510
COST OF THERAPY PER PATIENT (CHF)	97,083	100,450	100,450	100,450	100,450	100,450	100,450	100,450	100,450	100,450	100,450
SALES (CHF MN)	**0**	**0**	**0**	**0**	**0**	**16**	**25**	**34**	**41**	**47**	**51**
CHANGE (%)							56%	33%	22%	13%	10%
NET ROYALTY RATE (%)						19%	19%	17%	17%	17%	15%
NET ROYALTIES (CHF MN)	0	0	0	0	0	3	5	6	7	8	8
NET UPFRONT & MILESTONE PAYMENTS (CHF MN)	-10	0	0	15	10	0	0	0	5	0	0
R&D COSTS (CHF MN)	-16	-19	-19	-4	0	0	0	0	0	0	0
PROFIT BEFORE TAX (CHF MN)	**-25**	**-19**	**-19**	**11**	**10**	**3**	**5**	**6**	**12**	**8**	**8**
TAX RATE (%)	0%	0%	0%	0%	0%	0%	0%	0%	20%	20%	20%
TAXES (CHF MN)	0	0	0	0	0	0	0	0	-2	-2	-2
PROFIT (CHF MN)	**-25**	**-19**	**-19**	**11**	**10**	**3**	**5**	**6**	**10**	**6**	**6**

	2018E	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**
GLOBAL SALES (CHF MN)	**0**	**0**	**0**	**0**	**0**	**27**	**50**	**70**	**87**	**99**	**107**
CHANGE (%)							86%	40%	24%	14%	7%
GLOBAL PROFIT (CHF MN)	**-25**	**-19**	**-19**	**11**	**10**	**10**	**10**	**13**	**16**	**18**	**14**
CHANGE (%)		-23%	0%	-158%	-9%	1%	-6%	33%	25%	10%	-22%

WACC (%)	7%	
NPV TOTAL PROFIT (CHF MN)	**56**	
NUMBER OF SHARES (MN)	10.9	
NPV PER SHARE (CHF)	**5**	
SUCCESS PROBABILITY	50%	(PHASE II/III REGISTRATIONAL SUCCESS RATE)
RISK ADJUSTED NPV PER SHARE (CHF)	**3**	

SENSITIVITY ANALYSIS

		WACC (%)						
	CHF/SHARE	5.5	6.0	6.5	7.0	7.5	8.0	8.5
	100%	6	6	5	5	5	5	4
	90%	5	5	5	5	4	4	4
	80%	5	5	4	4	4	4	3
	70%	4	4	4	4	3	3	3
SUCCESS PROBABILITY	60%	4	3	3	3	3	3	3
	50%	3	3	3	**3**	2	2	2
	40%	2	2	2	2	2	2	2
	30%	2	2	2	2	1	1	1
	20%	1	1	1	1	1	1	1

ESTIMATES AS OF 12 SEPTEMBER, 2019

SOURCE: VALUATIONLAB ESTIMATES

Unique Selling Point

Potential to become the first effective treatment for inoperable or advanced iCCA patients who are FGFR2 fusion positive in a convenient once daily oral dose, which extends survival and improves quality of life in this small patient group with a poor prognosis and lack of treatments. Considerably more upside could come from large cancer indications where FGFR alteration is involved such as lung, breast and bladder cancer.

7P's Analysis

Patent: US: FGFR patent expires December 2029/January 2031 with up to 5-years patent term extension and 7-years orphan drug market exclusivity upon approval; EU: FGFR patent expires in December 2029 with up to 5-year SPC extension and 10-years orphan disease market exclusivity upon approval.

Phase: A phase II registrational biomarker-driven trial in iCCA with centers in the US, Canada, and Italy thus far, started in 2017. Basilea expects to run a phase III trial to receive US and EU approval, which could occur around 2023. US conditional approval could already occur in 2021 on positive results of the registrational phase II trial (conservatively not assumed in our forecasts). Basilea plans to start phase II POC trials in large cancer indications where FGFR alteration plays a role.

Pathway: Orphan drug designation was granted for iCCA in the US and EU, which speeds up development timelines, lowers development costs and hurdles, and the potential of priority review (e.g. 6 months review instead of 10 months regular review in the US).

Patient: A convenient once daily oral tablet that has the potential to improve survival and quality of life in patients with inoperable or advanced iCCA, which is well tolerated.

Physician: Potentially the first effective and well tolerated treatment for inoperable or advanced iCCA patients who are FGFR2 fusion positive, with the potential to improve survival and quality of life in otherwise patients with a poor prognosis due to an absence of effective treatments.

Payer: An improvement in survival and improvement of quality of life could lead to less overall treatment costs such as hospitalization or the use of ineffective chemotherapy or palliative treatments.

Partner: Basilea licensed the worldwide rights (excluding China, Hong Kong, Macau and Thailand) from ArQule in April 2018. ArQule received a USD 10 mn upfront payment from Basilea and is eligible to regulatory and sales milestones of up to USD 326 mn as well as staggered single to double-digit sales royalties. We assume Basilea seeks development and commercialization partners upon successful completion of development in iCCA or potentially earlier on positive proof-of-concept in other cancers such as bladder. From these partners, we assume 25% sales royalties and higher milestone payments than owed to ArQule for derazantinib in various cancer indications.

Pipeline – Emerging oncology pipeline

We have not accounted for Basilea's early stage projects focused on treatment-resistant cancer due to the current lack of clinical proof-of-concept. These projects could provide substantial upside when developed successfully.

Basilea's early stage clinical projects include:

1. **BAL101553** for treating refractory tumors, and potentially brain cancer
2. **BAL3833** for treating refractory tumors, including aggressive skin cancer unresponsive to current treatments

1) BAL101553 (solid tumors) – Targeting peak sales of CHF 500+ mn

BAL101553 is a so-called tumor checkpoint controller, which is being investigated for use in patients with advanced solid tumors. The drug targets markets such as the USD 3.5 bn taxane market, amongst others, where there is an increasing need for new agents in taxane-resistant cancer patients. Celgene's Abraxane is currently the largest-selling branded taxane achieving sales of almost USD 900 mn. Sanofi-aventis' Taxotere (docetaxel) peaked at USD 2 bn in 2010 before it lost its patent. Other resistant tumors such as glioblastoma (aggressive brain cancer) are also being targeted with BAL101553. Therefore, we believe peak sales of BAL101553 could easily reach CHF 500+ mn. Basilea is currently running three clinical trials in patients with glioblastoma where treatment options are limited with a poor prognosis.

Checkpoint controller with differentiation through a unique mode of action

BAL101553 is a synthetic small molecule anti-cancer drug candidate that destabilizes microtubules and acts as a so-called tumor checkpoint controller with an IV and oral formulation under development. BAL101553 is targeted to address the issue of frequent resistance to approved microtubule-targeting agents (MTA's), such as taxanes, epothilones and vinca-alkaloids. The compound has demonstrated to have broad activity in numerous cancer models refractory to these agents. Currently available data indicate a dual action of the drug by inducing tumor cell death and disrupting tumor blood supply. BAL27862, the active moiety of the water-soluble pro-drug BAL101553, binds tubulin at a site not targeted by approved MTA's that bind at a different tubulin site. Unlike approved MTA's, BAL101553 has the potential to be given with a daily oral regimen, as well as the more conventional intravenous route with an intermittent schedule (e.g. weekly). This provides a flexibility of dosing not possible with existing MTA's. BAL101553's different pharmacology, for instance it passes through the blood-brain-barrier, has the potential to open up development opportunities not addressed by standard MTA's, such as glioblastoma.

Comprehensive biomarker strategy unique to the field to improve tumor selection

Basilea is using a comprehensive dose- and patient-selection biomarker approach unique to the MTA field. Clinical dose evaluation is supported by pharmacodynamic biomarkers of tumor cell and tumor vascular response, where treatment effects on tumor cells and vascularization are shown. Basilea is guiding tumor selection for further clinical development through biomarker and epidemiology analyses. B1 is an example of a potential patient stratification marker, an important component of the spindle assembly checkpoint, required for the activity of BAL101553 in vitro.

Basilea is currently running three clinical trials with BAL101553 in glioblastoma
BAL101553 is available in an intravenous (IV) and oral formulation. The IV formulation, given as a 2-hour infusion, successfully completed phase I/IIa development in 2016. Based on the encouraging data, Basilea started a second IV trial with a portable continuous pump (48-hour infusion) in patients with advanced solid tumors in 2016, as well as a phase I/IIa trial with the oral formulation given once daily. An additional arm including glioblastoma patients was added to this trial in December 2016.

In June 2018, data from the phase I dose-escalation parts of the two phase I/IIa trials with weekly continuous pump (48-hour infusion) and once daily oral dosing were presented at the ASCO (American Society of Clinical Oncology) annual meeting in Chicago. BAL101553 showed initial signals of clinical activity as monotherapy and an acceptable safety profile supporting further investigation into phase IIa development in targeted patient populations.

BAL101553 clinical trials in glioblastoma:

1) **United Kingdom:** a phase I dose escalation trial is ongoing in recurrent or progressive glioblastoma patients with daily oral administration to assess safety at various dose levels; completion of enrollment in August 2019
2) **Switzerland:** phase IIa expansion trial in patients with recurrent glioblastoma using weekly continuous pump (48-hour infusion); a separate arm in this trial includes patients with platinum-resistant ovarian cancer; started in June 2018 with top line results due in year-end 2019
3) **United States:** phase I trial in newly diagnosed glioblastoma patients with first-line daily oral BAL101553 in combination with radiotherapy conducted in collaboration with the Adult Brain Tumor Consortium (ABTC); started in January 2018 with top line results due in 2-3 years

First POC in glioblastoma established in UK trial with a long-lasting responder
In December 2016, Basilea expanded the phase I dose-escalation part of its ongoing phase I/IIa trial with the daily oral formulation to include a separate trial arm for patients with glioblastoma, where there are currently limited effective treatment options for this aggressive and often lethal brain cancer. BAL101553 has shown to enter the brain and demonstrated anticancer activity with oral dosing in various preclinical models of glioblastoma, including models refractory to or with reduced sensitivity to standard therapies. Complete enrollment of the phase I part of the trial occurred in August 2019. In 28 patients with recurrent glioblastoma an MTD (maximum tolerated dose) was established at 30 mg (doses up to 25 mg/day were well tolerated) with 1 long-lasting responder with EB-1 (plus-end binding protein) biomarker still on treatment, while 5 other patients experienced stable disease. EB1 is located on the microtubules and involved in microtubule dynamics and is predictive of response to BAL101553 in mouse models. Strong EB1 staining was observed in the long-lasting responder with treatment ongoing for more than 15 months with an approximately 70% reduction in GBM tumor size. The potential use of EB1 to support a biomarker-driven clinical trial program is being assessed.

Phase I/IIa weekly 2-hours infusion trial completed with compelling early results…
The IV formulation of BAL101553 completed phase I/IIa with compelling early results. The maximum tolerated dose (MTD) for weekly 2-hours IV administration was established (60 mg/m2) and a phase II dose was recommended (30 mg/m2), while there were early indications of clinical benefit. Tumor types in the phase IIa part of the POC trial were selected based on a detailed pre-clinical profiling of potential response biomarkers across tumor

indications, including colorectal, gastric, non-small cell lung, ovarian, pancreatic and triple-negative breast cancer. Of the 59 evaluable patients there was 1 prolonged partial response (>2 years on drug) and 14 disease stabilizations. Pharmacodynamic effects were observed in tumor biopsies post treatment and a patient biomarker evaluation strategy was included (including for instance BubR1).

…leading to a Swiss phase I/IIa trial with continuous pump (48-hour infusion)
Based on the evidence of clinical anti-tumor activity in the phase I/IIa trial with 2-hour IV dosing, Basilea decided to start a new phase I/IIa trial of BAL101553 with a 48-hours dosing regimen in patients with advanced solid tumors in September 2016. Continuous infusion with portable pumps is an established mode of drug administration and could provide additional administration flexibility and optimize pharmacodynamics effects beyond weekly 2-hours IV infusion or daily oral administration. The phase I part of the trial establishing maximum tolerated dose (MTD) has been completed and was presented at ASCO in June 2018 showing early signals of efficacy with an acceptable safety profile. A phase IIa expansion trial in patients with recurrent glioblastoma using weekly continuous pump (48-hour infusion) was started in June 2018. A separate arm in this trial includes patients with platinum-resistant ovarian cancer. Top line results are expected to report by year-end 2019.

ABTC conducts a US phase I trial of daily oral in newly diagnosed glioblastoma
In June 2017, a clinical trial agreement was reached with the Adult Brain Tumor Consortium (ABTC) to explore the use of daily oral BAL101553 in newly diagnosed glioblastoma, the most common primary brain tumor and one of the most lethal types of cancer. The ABTC is designed to develop more effective treatments for malignant brain tumors and is funded by the US National Cancer Institute and has 11 brain tumor centers at leading universities across the US. In January 2018, in collaboration with ABTC, a phase I trial was started with the oral formulation of BAL101553 in combination with standard radiation in patients with newly diagnosed glioblastoma who have a reduced sensitivity to chemotherapy due to an unmethylated MGMT promotor. MGMT promotor methylation status determines whether DNA-damaging standard chemotherapy with temozolimide makes sense. The trial started is largely paid for by ABTC, where Basilea provides BAL101553 while ABTC conducts the trial. Top line results can be expected in 2-3 years' time (early 2020 or 2021). The ABTC agreement underlines the potential of BAL101553 in glioblastoma where treatment options are limited and is an important external validation.

Strong oncology partner required given the amount of potential indications
Basilea plans to move BAL101553 into pivotal development only with a partner. Given the amount of potential indications, further development requires a strong player in the oncology field with sufficient development expertise and resources to tackle the broad scope of BAL101553 successfully. Basilea has already shared available data with several players and we expect positive results in glioblastoma patients to trigger a major partnering agreement. This could happen on strong early signals in the phase I daily oral trial in the UK, but more likely on completion of the Swiss phase IIa continuous pump (48-hour infusion) trial results expected by year-end 2019. Applying industry timelines for the development of cancer drugs, a launch may be anticipated in 7 to 8 years.

2) BAL3833 (melanoma/solid tumors) – Next cancer drug to boost value

In April 2015 Basilea in-licensed BAL3833, a unique panRAF/SRC kinase inhibitor, from a consortium of organizations including the Institute of Cancer Research, London, Cancer Research Technology, the Wellcome Trust and the University of Manchester, for undisclosed terms. It is an orally available small-molecule inhibitor of the RAF and SRC kinase families, targeting certain cell proliferation signaling pathways that are associated with tumor growth.

Unique kinase inhibition profile targeting e.g. treatment-resistant skin cancer

BAL3833 is targeted to address the issue of frequent resistance to approved mutant BRAF inhibitors, such as Roche's Zelboraf (vemurafenib) and Novartis' Tafinlar (dabrafenib), which are used to treat melanoma (aggressive skin cancer), alone or in combination with MEK kinase inhibitors such as Novartis' Mekinist (trametinib). BAL3833 has an extended profile to the current BRAF inhibitors. Next to targeting mutant and non-mutated BRAF, its signaling partner CRAF is also targeted, as well as SRC, another important kinase involved in tumor progression. Both CRAF and SRC are largely involved in tumor progression and the development of resistance. In multiple tumor models derived from melanoma patients progressing on standard BRAF treatment, as well as in models derived from non-melanoma types, BAL3833 has shown potent anti-cancer activity. Based on its unique kinase inhibition profile, BAL3833 has potential to be used in drug refractory and non-BRAF mutated melanoma as well as in other tumor types not necessarily associated with BRAF mutation, including colorectal, pancreatic, and non-small cell lung cancer.

Positive POC could trigger lucrative partnership with peak sales of CHF ~500 mn

BAL3833 is being developed using a comprehensive dose- and patient-selection biomarker approach. A phase I dose-escalation trial in advanced solid tumor patients, including metastatic melanoma, refractory to current therapy was started in May 2015. Basilea's partner, the Institute of Cancer Research completed enrollment in the phase I dose-escalation trial, where a broad dose was investigated. A maximum tolerated dose was not defined. The current formulation will not be continued based on the pharmacokinetic profile. Basilea is conducting pre-clinical activities to explore alternative formulations for BAL3833. Successful completion would allow Basilea to start a phase IIa trial to evaluate specific indications to establish POC. Positive POC results could trigger a lucrative co-development and co-promotion agreement with a large cancer player. Applying industry timelines for the development of cancer drugs, a launch may be anticipated in 7 to 8 years.

Sales of Novartis' Tafinlar + Mekinist, a fixed combination treatment of a BRAF and MEK kinase inhibitor for metastatic melanoma, launched in 2014, rapidly grew to USD 1.2 bn in 2018; with consensus peak sales of more than USD 1.5 bn, indicating BAL3833 peak sales could easily reach CHF ~ 500 mn given its unique kinase inhibition profile.

Income Statement

BASILEA PHARMACEUTICA										SHARE PRICE (CHF)	46.1
US GAAP											
INCOME STATEMENT (CHF MN)	**2018**	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**
PRODUCT SALES (INCLUDING PARTNER SALES)	**165**	**223**	**286**	**360**	**517**	**769**	**998**	**1'143**	**1'256**	**1'226**	**827**
CHANGE (%)	70%	35%	28%	26%	43%	49%	30%	14%	10%	-2%	-33%
PRODUCT REVENUES (BOOKED BY BASILEA)	**26**	**37**	**44**	**31**	**60**	**106**	**152**	**151**	**156**	**132**	**69**
CHANGE (%)	27%	42%	19%	-30%	96%	75%	44%	-1%	3%	-15%	-48%
ROYALTIES (FROM PARTNERS)	**26**	**36**	**44**	**53**	**71**	**98**	**126**	**151**	**173**	**171**	**117**
CHANGE (%)	77%	35%	23%	21%	34%	38%	29%	20%	14%	-1%	-31%
CONTRACT REVENUE (INCL. MILESTONES/EX. ROYALTIES)	**53**	**33**	**13**	**122**	**87**	**46**	**65**	**65**	**65**	**67**	**28**
CHANGE (%)	-10%	-38%	-60%	834%	-29%	-47%	40%	0%	0%	3%	-58%
OTHER REVENUES	**27**	**24**	**24**	**12**	**1**	**1**	**1**	**1**	**1**	**1**	**1**
+ REVENUE FROM R&D SERVICES	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
+ OTHER REVENUE:	26	23	23	12	0	0	0	0	0	0	0
+ BARDA REVENUE	26	23	23	12	0	0	0	0	0	0	0
+ OTHERS	0.6	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
TOTAL REVENUES (EXCL. PARTNER SALES)	**133**	**129**	**124**	**218**	**219**	**250**	**344**	**368**	**394**	**371**	**215**
CHANGE (%)	25%	-2%	-4%	75%	0%	14%	37%	7%	7%	-6%	-42%
COGS	**-20**	**-23**	**-18**	**-10**	**-18**	**-32**	**-42**	**-41**	**-37**	**-31**	**-17**
GROSS PROFIT	**112**	**106**	**107**	**208**	**201**	**218**	**302**	**327**	**357**	**340**	**198**
CHANGE (%)	16%	-6%	1%	95%	-4%	9%	38%	8%	9%	-5%	-42%
MARGIN (%)	85%	82%	86%	95%	92%	87%	88%	89%	91%	92%	92%
R&D	**-105**	**-105**	**-105**	**-104**	**-62**	**-63**	**-64**	**-65**	**-66**	**-67**	**-68**
CHANGE (%)	96%	0%	0%	-1%	-40%	2%	2%	2%	2%	2%	1%
S,G&A	**-31**	**-31**	**-27**	**-26**	**-26**	**-27**	**-27**	**-26**	**-25**	**-25**	**-26**
CHANGE (%)	-41%	-2%	-13%	-3%	1%	1%	1%	-4%	-1%	0%	0%
OPERATING EXPENSES	**-157**	**-159**	**-150**	**-140**	**-106**	**-122**	**-133**	**-132**	**-129**	**-124**	**-110**
CHANGE (%)	35%	2%	-6%	-6%	-24%	15%	9%	-1%	-2%	-4%	-11%
EBIT	**-24**	**-30**	**-25**	**78**	**112**	**128**	**211**	**236**	**265**	**247**	**104**
CHANGE (%)	145%	25%	-16%	-409%	44%	14%	64%	12%	12%	-7%	-58%
MARGIN (%)	-18.2%	-23.3%	-20.3%	35.7%	51.4%	51.3%	61.4%	64.2%	67.3%	66.7%	48.6%
EBITDA	**-22**	**-27**	**-21**	**83**	**119**	**136**	**220**	**246**	**277**	**260**	**118**
CHANGE (%)	184%	22%	-23%	-497%	43%	14%	62%	12%	12%	-6%	-55%
MARGIN (%)	-16.8%	-21.0%	-16.9%	38.2%	54.4%	54.4%	64.0%	67.0%	70.3%	70.1%	55.1%
D&A	**2**	**3**	**4**	**5**	**7**	**8**	**9**	**10**	**11**	**13**	**14**
NET INTEREST INCOME/(EXPENSE)	**-7**	**-7**	**-7**	**-7**	**-7**	**0**	**0**	**0**	**0**	**0**	**0**
NET OTHER FINANCIAL INCOME/(EXPENSES)	**-1**	**1**	**2**	**2**	**3**	**4**	**4**	**6**	**7**	**8**	**10**
OTHER COMPONENTS OF NET PERIODIC PENSION COST	1	1	1	1	1	1	1	1	1	1	1
PROFIT BEFORE TAXES	**-31**	**-34**	**-29**	**75**	**110**	**133**	**217**	**243**	**273**	**257**	**116**
CHANGE (%)	112%	10%	-16%	-357%	47%	21%	63%	12%	13%	-6%	-55%
MARGIN (%)	-24%	-27%	-23%	34%	50%	53%	63%	66%	69%	69%	54%
TAXES	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**-71**	**-68**	**-39**
NET PROFIT/LOSS	**-31**	**-35**	**-29**	**74**	**110**	**133**	**216**	**243**	**202**	**189**	**77**
CHANGE (%)	108%	10%	-15%	-355%	47%	21%	63%	12%	-17%	-6%	-59%
MARGIN (%)	-24%	-27%	-23%	34%	50%	53%	63%	66%	51%	51%	36%
EPS (CHF)	**-2.89**	**-2.91**	**-2.46**	**6.27**	**9.22**	**11.19**	**18.21**	**20.42**	**17.01**	**15.91**	**6.50**

ESTIMATES AS OF 16 SEPTEMBER, 2019 SOURCE: VALUATIONLAB ESTIMATES

FY 2019 guidance:

- **Total revenue:** CHF 128-133 mn (note: despite the end of Toctino contract revenue worth CHF 23.9 mn in 2018)
- **Cresemba and Zevtera revenue:** CHF 105-110 mn (+28% to +34% increase)
- **Total operating expenses:** approximately same as in FY 2018 (CHF 157 mn)
- **Operating loss:** CHF 22-27 mn
- **Net operating cash consumption:** CHF 60-65 mn

Total Revenues – Breakdown

BASILEA PHARMACEUTICA										SHARE PRICE (CHF)	46.1
US GAAP											
INCOME STATEMENT (CHF MN)	**2018**	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**	**2027E**	**2028E**
PRODUCT SALES (INCLUDING PARTNER SALES)	**165**	**223**	**286**	**360**	**517**	**769**	**998**	**1'143**	**1'256**	**1'226**	**827**
CHANGE (%)	70%	35%	28%	26%	43%	49%	30%	14%	10%	-2%	-33%
PRODUCT REVENUES (BOOKED BY BASILEA)	**26**	**37**	**44**	**31**	**60**	**106**	**152**	**151**	**156**	**132**	**69**
CHANGE (%)	27%	42%	19%	-30%	96%	75%	44%	-1%	3%	-15%	-48%
ROYALTIES (FROM PARTNERS)	**26**	**36**	**44**	**53**	**71**	**98**	**126**	**151**	**173**	**171**	**117**
CHANGE (%)	77%	35%	23%	21%	34%	38%	29%	20%	14%	-1%	-31%
CONTRACT REVENUE (INCL. MILESTONES/EX. ROYALTIES)	**53**	**33**	**13**	**122**	**87**	**46**	**65**	**65**	**65**	**67**	**28**
CHANGE (%)	-10%	-38%	-60%	834%	-29%	-47%	40%	0%	0%	3%	-58%
+ 1) DEFERRED REVENUES IN CONTRACT REVENUE:	**53**	**33**	**13**	**30**	**34**	**43**	**62**	**52**	**62**	**64**	**25**
A) STIEFEL: CHF 224.1 MN UPFRONT FOR TOCTINO (2012)	**23.9**										
B) DISTRIBUTION AGREEMENTS:	**3.7**	**1.2**	**1.2**	**1.2**	**1.2**	**1.2**	**1.2**	**1.2**	**1.2**	**1.2**	**1.2**
+ OTHER DISTRIBUTORS: CHF 12.1 MN (2016)	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8
+ OTHER DISTRIBUTORS: CHF 6.3 MN (2017)	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
+ OTHER DISTRIBUTORS CONTRACT REVENUE (OTHERS)	0.5										
+ GBT CHF 2 MN REGULATORY MILESTONE (2017)											
+ GBT CHF 2 MN REGULATORY MILESTONE (2018)	2.0										
C) ASTELLAS (2010: CRESEMBA USA)	**20.7**	**24.8**	**10.0**	**0.0**	**20.9**	**0.0**	**24.7**	**0.0**	**12.0**	**0.0**	**0.0**
+ ASTELLAS: CHF 67.5 MN UPFRONT MILESTONE (2010)	4.5	4.5	4.0								
+ ASTELLAS: CHF12 MN FILING MILESTONE (2012)	1.8	1.8	1.6								
+ ASTELLAS: CHF 30 MN APPROVAL ASPERGILLUS (2015)	4.4	4.4	4.4								
+ ASTELLAS: CRESEMBA SALES MILESTONES (DIRECT)	10	14	0	0	21	0	25	0	12	0	0
D) ASTELLAS (SERVICE REV. ISA. (EX. ROYALTIES)	**0.2**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
E) ASAHI KASEI (2016: CRESEMBA JAPAN)	**1.3**	**1.3**	**1.3**	**6.3**	**7.1**	**2.5**	**3.5**	**4.4**	**5.0**	**5.6**	**1.7**
+ ASAHI KASEI: CHF 7 MN UPFRONT (2016)	1.3	1.3	1.3	1.3	0.1	0.0	0.0	0.0	0.0	0.0	0.0
+ ASAHI KASEI: CRESEMBA MILESTONES (DIRECT)	0.0	0.0	0.0	5.0	7.0	2.5	3.5	4.4	5.0	5.6	1.7
F) PFIZER (2017: CRESEMBA EUROPE, RUS, TRKY, ISR)	**0.0**	**5.0**	**0.0**	**20.1**	**0.0**	**28.1**	**30.1**	**35.2**	**40.2**	**38.2**	**0.0**
+ PFIZER: CRESEMBA SALES MILESTONES (DIRECT)		5.0	0.0	20.1	0.0	28.1	30.1	35.2	40.2	38.2	0.0
G) PFIZER (2018: CRESEMBA CHINA, HK, MACAO)	**2.9**	**0.0**	**0.0**	**0.0**	**0.0**	**10.0**	**0.0**	**8.0**	**0.0**	**15.1**	**18.1**
+ PFIZER: USD 3 MN (CHF 2.9 MN) UPFRONT (2018)	2.9										
+ PFIZER: CRESEMBA SALES MILESTONES (DIRECT)	0.0	0.0	0.0	0.0	0.0	10.0	0.0	8.0	0.0	15.1	18.1
H) CR GOSUN (2017: ZEVTERA CHINA, HK, MACAO)	**0.6**	**0.6**	**0.6**	**2.6**	**5.1**	**1.4**	**2.2**	**2.9**	**3.5**	**3.9**	**4.1**
+ CR GOSUN: CHF 3 MN UPFRONT (SEP 2017)	0.6	0.6	0.6	0.6	0.1	0.0	0.0	0.0	0.0	0.0	0.0
+ CR GOSUN: ZEVTERA SALES MILESTONES (DIRECT)	0.0	0.0	0.0	2.0	5.0	1.4	2.2	2.9	3.5	3.9	4.1
+ 2) DERAZANTINIB (ICCA) (DEFERRED REVENUES, NET)	**0**	**0**	**0**	**2**	**3**	**3**	**3**	**3**	**3**	**3**	**3**
+ 3) ZEVTERA US UPFRONT & MILESTONE PAYMENTS	**0**	**0**	**0**	**90**	**50**	**0**	**0**	**10**	**0**	**0**	**0**
+ **US PARTNER:** ZEVTERA ABSSSI	0.0	0.0	0.0	30.1	20.1	0.0	0.0	0.0	0.0	0.0	0.0
+ **US PARTNER:** ZEVTERA SAB	0.0	0.0	0.0	60.3	30.1	0.0	0.0	10.0	0.0	0.0	0.0
OTHER REVENUES	**27**	**24**	**24**	**12**	**1**	**1**	**1**	**1**	**1**	**1**	**1**
+ REVENUE FROM R&D SERVICES	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
+ OTHER REVENUE:	26	23	23	12	0	0	0	0	0	0	0
+ BARDA REVENUE	26	23	23	12	0	0	0	0	0	0	0
+ OTHERS	0.6	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
TOTAL REVENUES (EXCL. PARTNER SALES)	**133**	**129**	**124**	**218**	**219**	**250**	**344**	**368**	**394**	**371**	**215**
CHANGE (%)	25%	-2%	-4%	75%	0%	14%	37%	7%	7%	-6%	-42%

Breakdown of Basilea's Total Revenues.

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)).

Basilea follows US GAAP accounting where upfront milestones are typically deferred over the contract period, while sales milestones are typically booked when received.

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) 46.1

RATIOS	2018	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
P/E		-15.8x	-18.7x	7.4x	5.0x	4.1x	2.5x	2.3x	2.7x	2.9x	7.1x
P/S		4.2x	4.4x	2.5x	2.5x	2.2x	1.6x	1.5x	1.4x	1.5x	2.6x
P/NAV		-4.2x	-2.9x	-4.4x	-2.4x	-4.8x	6.9x	1.8x	1.1x	0.8x	0.7x
EV/EBITDA		-12.8x	-16.5x	4.2x	2.9x	2.5x	1.6x	1.4x	1.3x	1.3x	2.9x

PER SHARE DATA (CHF)	2018	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
EARNINGS	**-2.89**	**-2.91**	**-2.46**	**6.27**	**9.22**	**11.19**	**18.21**	**20.42**	**17.01**	**15.91**	**6.50**
CHANGE (%)	108%	1%	-15%	-355%	47%	21%	63%	12%	-17%	-6%	-59%
CASH	**20.58**	**13.45**	**8.68**	**12.74**	**3.01**	**12.19**	**28.49**	**47.10**	**62.41**	**76.71**	**81.70**
CHANGE (%)	-14%	-35%	-35%	47%	-76%	305%	134%	65%	33%	23%	7%
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	**-6.15**	**-10.94**	**-15.71**	**-10.38**	**-19.26**	**-9.67**	**6.64**	**25.25**	**40.98**	**55.70**	**64.99**
CHANGE (%)	80%	78%	44%	-34%	86%	-50%	-169%	280%	62%	36%	17%

BALANCE SHEET (CHF MN)	2018	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
NET LIQUID FUNDS	**223**	**160**	**103**	**151**	**36**	**145**	**338**	**560**	**741**	**911**	**971**
TOTAL ASSETS	**282**	**219**	**162**	**210**	**94**	**203**	**397**	**618**	**800**	**970**	**1'029**
FINANCIAL DEBT	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
AS PERCENTAGE OF TOTAL ASSETS (%)	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
TOTAL SHAREHOLDERS' EQUITY	**-67**	**-130**	**-187**	**-123**	**-229**	**-115**	**79**	**300**	**487**	**662**	**772**
CHANGE (%)											
RETURN ON EQUITY (%)	47%	27%	16%	-60%	-48%	-116%	274%	81%	42%	29%	10%
EMPLOYEES	225	220	220	220	220	220	220	220	220	220	220
CHANGE (%)	2%	-2%	0%	0%	0%	0%	0%	0%	0%	0%	0%

CASH FLOW STATEMENT (CHF MN)	2018	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
NET PROFIT / (LOSS)	**-31**	**-35**	**-29**	**74**	**110**	**133**	**216**	**243**	**202**	**189**	**77**
DEPRECIATION & AMORTIZATION	2	3	4	5	7	8	9	10	11	13	14
OTHER NON-CASH ITEMS	-57	-32	-32	-32	-32	-32	-32	-32	-32	-32	-32
NET CASH FLOW FROM OPERATING ACTIVITIES	**-79**	**-63**	**-57**	**48**	**84**	**109**	**194**	**221**	**182**	**170**	**59**
NET CASH FLOW FROM INVESTING ACTIVITIES	**59**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
NET CASH FLOW USED IN OPERATING ACTIVITIES	**-20**	**-63**	**-57**	**48**	**84**	**109**	**194**	**221**	**182**	**170**	**59**
NET CASH FLOWS FROM FINANCING ACTIVITIES	-6	0	0	0	-200	0	0	0	0	0	0
FX RATE CHANGES ON CASH AND CASH EQUIVALENTS	-1										
NET CHANGE IN CASH & CASH EQUIVALENTS	**-27**	**-63**	**-57**	**48**	**-116**	**109**	**194**	**221**	**182**	**170**	**59**

ESTIMATES AS OF 16 SEPTEMBER, 2019

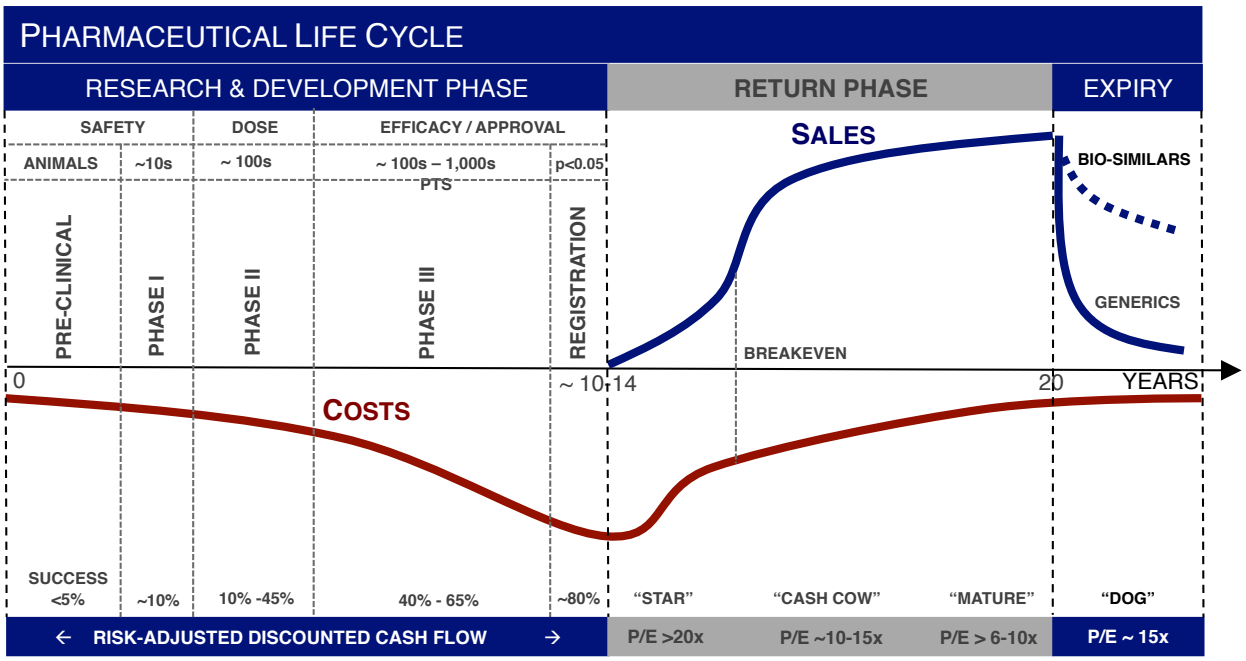
SOURCE: VALUATIONLAB ESTIMATES

NOTE: With cash and financial investments of CHF 178 mn (30 June 2019), a BARDA contract worth up to USD 128 mn in funding, first revenues from Zevtera in severe lung infections (EU/ROW) and from Cresemba in invasive mold infections, Basilea has sufficient cash to approach profitability in 2020/2021, in our view.

APPENDIX

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 EU, 7 years in 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 IIa 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

Important Research Disclosures

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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.

Purpose of the Research

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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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