Basilea Pharmaceutica

25 September 2025

Share Price (CHF)	**46**
CP Fair Value (CHF)	**120**
Market Cap (CHFm)	**602**
Net Cash (CHFm)	**50**
EV (CHFm)	**55**
Country	Switzerland
Code	BSLN
Index	SIX

Infectious growth

The recent past at Basilea has been dominated by the rejuvenated outlook for the antifungal franchise, with the Phase 3 programme for the novel antifungal fosmanogepix now underway. We believe it's easy to get excited about the potential of fosmanogepix, given its activity against most of the WHO priority pathogens, as well as its extended spectrum compared to Basilea's maturing but very successful Cresemba (isavuconazole). More recently, it has been Fosmanogepix's excellent performance against apparently intractable, life-threatening fungal infections, as part of an expanded access programme, that has provided valuable insights into its treatment of fungal infections generally and its importance as an addition to the physician's armamentarium. Our peak sales estimate for fosmanogepix is $1.2bn, based on its clinical profile.

Fosmanogepix moving through Phase 3

The Phase 3 clinical programme for fosmanogepix is now underway, targeting the treatment of candidaemia and/or invasive candidiasis, as well as invasive mould infections. The profile of fosmanogepix suggests that it should provide longevity to the antifungal franchise after the expected loss of exclusivity for Cresemba in the US and Europe in Q4 2027. Based on its profile and clinical data, we also forecast fosmanogepix will comfortably exceed peak sales of Cresemba. The importance of fosmanogepix has been reflected in FDA conferring QIDP and Fast Track status for invasive aspergillosis, candidiasis, scedosporiosis, fusariosis, cryptococcosis, coccidioidomycosis and mucormycosis. Encouraging Phase 2 data suggests the Phase 3 programme has been substantially de-risked.

Multiple growth drivers

Management's endeavours to extend and grow the anti-infective franchise at Basilea feature extensive licensing activities. We look forward to progress updates from the launch phase of Zevtera in the US through Innoviva Specialty Therapeutics (IST), particularly as it relates to the bacteraemia (SAB) indication. The recent in-licensing of the Phase 3-ready programme, ceftibuten-ledaborbactam etzadroxil, represents a validated approach to reverse resistance targeting complicated urinary tract infections (cUTI), caused by resistant strains of Enterobacterales. Phase 3 is expected to begin in 2027, and we look forward to this programme contributing to the franchise from 2029E. We have introduced sales to our model based on the positive susceptibility data and profile. Basilea's efforts to expand its pipeline have been ably supported by the receipt of non-dilutive funding, particularly from the Biomedical Advanced Research and Development Authority (BARDA). The award of the Other Transaction Agreement (OTA) has allowed for potential funding of up to $268 million over 12 years. This amount represents approximately 60% of the total development costs. Additionally, up to $159m has been made available from BARDA for the ceftibuten-ledaborbactam programme. The flexibility that the BARDA relationship allows portends well for the future success of Basilea's anti-infective endeavours.

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Creating a world leading anti-infectives franchise

Delivering success in anti-infectives

Basilea has proven that being a leading participant in the delivery of medically and commercially relevant anti-infectives can be a lucrative and fulfilling endeavour. To date, this has largely been thanks to the continued success of the antifungal Cresemba and the efforts of its licensees, particularly Astellas in the US and Pfizer (Europe ex. Nordics). While Cresemba may be maturing, with loss of exclusivity expected in the US (September 2027) and Europe (October 2027), it continues to grow. It is now the leading branded antifungal by sales globally.

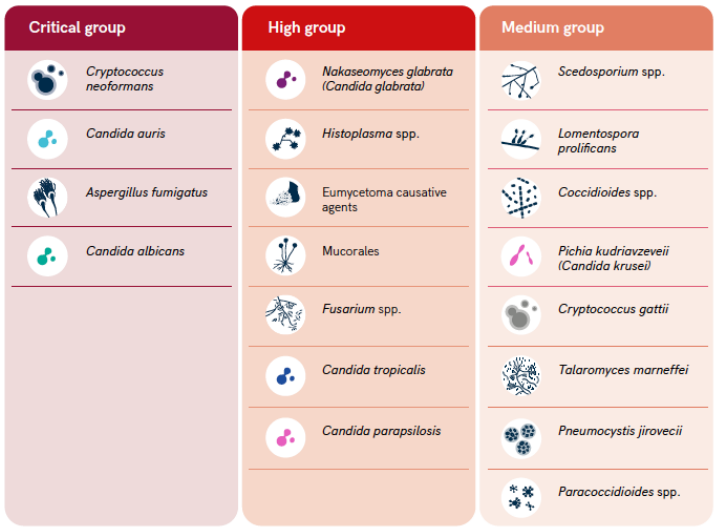
Exciting pipeline of new antifungals becoming evident

The financial performance of Cresemba has facilitated the creation of a broad anti-infective pipeline; however, it is the antifungal franchise that we remain most enthused about. In addition, recent efforts to build the anti-bacterial pipeline look highly promising. Thankfully, the pipeline of novel antifungals generally looks healthier, partly, we suspect, due to the WHO's efforts to raise awareness and foster a sense of urgency to deliver new antifungal agents.

Awareness of the growing threat from emerging antifungal infections has been heightened by the WHO, which published a list of critical fungal infections for the first time in 2022. This has significantly increased the profile and industry participation in the development of novel antifungal treatments.

WHO fungal priority pathogens list

WHO involvement notable



Source: World Health Organization

BARDA OTA transformational

Securing a multi-year Other Transaction Agreement (OTA), which provides up to $268m of funding over up to 12 years, represented a key transformational event for the company. BARDA utilises OTAs to "…*foster innovation and promote collaboration."* They are a key element of the US government's preparedness for various threats,

including, in the case of Basilea, emerging infectious disease threats.

The antifungal franchise future

Antifungals are the key for now

Although the therapeutic focus for Basilea comprises both antifungals and anti-bacterials, there is a recognition that antifungals offer a larger commercial opportunity. The risk of serious invasive fungal infections continues to increase as procedures that drive growth in the immunocompromised patient population increase. These are well-understood and include organ transplantation and more aggressive cancer treatments. Emerging resistance has also become a significant issue.

Cresemba continues to deliver for Basilea and its licensees

It is important to note that while Cresemba may be subject to loss of exclusivity from late 2027 in the US and Europe, it is still very much in its growth phase despite this apparent maturity, delivering sales of $612m (+25% YoY) in the 12 months to the end of March 2025.

Building a relevant antifungal pipeline

The first addition to Basilea's antifungal pipeline was BAL2062 (formerly GR-2397), a novel first-in-class antifungal agent with activity against clinically important moulds such as *Aspergillus spp*, including those resistant to currently available therapies. The commercial relevance of this acquisition is clear, with invasive aspergillosis the principal revenue generator for Cresemba, and potentially providing an alternative where resistance is suspected.

Fosmanogepix targets most critical fungal infections

The acquisition of fosmanogepix, on the other hand, has been a transformational de-risking event and promises to take the anti-infective franchise to new heights. Crucially, fosmanogepix demonstrates activity against almost all the problem fungal infections highlighted on the WHO list. As such, should the Phase 3 programme confirm its broad spectrum and clinical activity, we believe that commercial success is assured.

Fosmanogepix's promise

First in the new "gepix" class

We have previously highlighted the very attractive profile of fosmanogepix. As the first from the new 'gepix' class, fosmanogepix (a prodrug of manogepix) inhibits fungal cell wall synthesis by targeting GPI-anchored protein maturation by inhibiting Gwt1 in the GPI biosynthesis pathway. Despite its evolutionary conservation, there are significant differences in the GPI pathway between humans and other organisms, enabling the development of inhibitors with excellent selectivity. This apparent selectivity has been borne out in the clinical studies confirming its benign safety profile.

No direct competition

We are aware of only two novel antifungals with activity against Gwt1. One of which is fosmanogepix, while gepinacin development has been compromised by its instability, offering no competition to fosmanogepix.

Oral and IV preparations

Preclinical and clinical data suggest that fosmanogepix has a differentiated and highly relevant profile. It has high bioavailability (>90%), providing the potential for both oral and IV preparations. This is relevant to the extent that the echinocandins can only be delivered by the IV route. The importance of echinocandins lies in their role as the first-line treatment for *Candida auris* infections, where increasing resistance to the azoles has become a growing concern.

Taking the antifungal franchise to new heights

We believe that fosmanogepix, with its broad-spectrum activity against all priority pathogens, as well as resistant fungal infections, could take the anti-infectives franchise at Basilea to new heights. More recently, *C. auris* and *Nakaseomyces glabrata* have proven to be problematic fungal infections in the US. Moreover, fosmanogepix post-approval should possess a much broader label than Cresemba. Importantly, fosmanogepix has also demonstrated activity against other rare, difficult-to-treat moulds that were typically resistant to other antifungal agents. Furthermore, fosmanogepix possesses activity against *Aspergillus* resistant to echinocandins and fluconazole.

Good tissue distribution into key organs is a key attribute

The broad spectrum and potency of fosmanogepix have been demonstrated in various animal models. Several key attributes have been confirmed, including its ability to reduce fungal burden, particularly in key organs such as the brain, where the echinocandins have negligible activity. Overall, fosmanogepix has a good volume of distribution, penetrating many important tissues and organs, including liver, lung, and eye. As a novel first-in-class antifungal, resistance to fosmanogepix should be a distant concern in a real-world environment.

Resistance is a distant concern

Fosmanogepix's clinical development

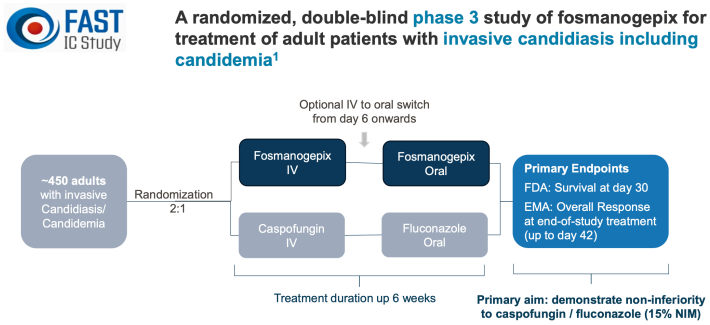
Three Phase 2 studies have been completed in patients with candidaemia, including those caused by *C. auris* and invasive mould infections. *C. auris* has been associated with high mortality rates (circa 60%) in patients hospitalised with a *C.auris* infection. Resistance to existing classes of antifungals has been a characteristic of almost all *C. auris* strains. The rapid emergence of *C. auris,* with its multidrug resistance and associated high mortality rate, has led various health authorities to highlight it as a fungal infection of significant concern. In the US, the CDC has highlighted the increasing prevalence of *C. auris* infections. Consequently, CDC has designated *C. auris* as an urgent antimicrobial resistance threat in the US. In March 2023, the CDC issued a warning regarding the increasing risk of infection from drug-resistant *C. auris* following a spike in cases in California.

Supportive Phase 2 data

Phase 3 in progress

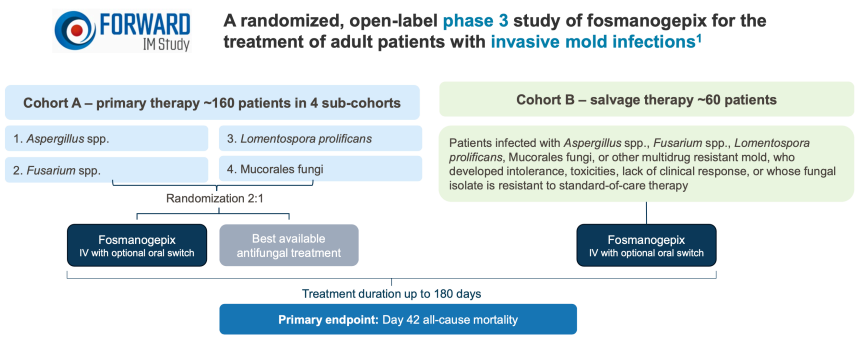
Reflecting the unmet need and the commercial opportunity, the two Phase 3 trials comprise one targeting candidaemia/invasive candidiasis, and a second targeting invasive mould infections.

Global phase 3 study in invasive candidiasis



Source: Basilea investor presentation

Global phase 3 study in invasive mold infections



Source: Basilea investor presentation

Oral step-down desirable

The first Phase 3 study - Fosmanogepix Against Standard-of-care Treatment in Invasive Candidiasis (FAST-IC), was initiated in September 2024. This study is a global, randomised, double-blind trial designed to demonstrate non-inferiority to the standard of care. The trial aims to enrol 450 patients and will compare fosmanogepix to caspofungin, both of which offer oral step-down options. The primary endpoint agreed with FDA is 30-day survival, while for EMA approval, the primary endpoint is overall response at the end of study treatment.

Invasive mould study is also now underway

The invasive mould (FORWARD-IM) study is an open-label, randomised trial, and is expected to enrol approximately 220 patients. The study aims to compare fosmanogepix versus best available therapy against a broad range of clinically and commercially relevant invasive fungal infections, including Invasive aspergillosis (IA), *Fusarium spp.*, *Scedosporium spp.*, *Mucorales*, *Lomentospora prolificans,* as well as other multi-drug-resistant moulds. This study was initiated in July 2025. Given that fosmanogepix has obtained Fast Track status from FDA for seven different fungal infections, we believe that it will be relevant to a broad range of critical fungal pathogens.

Phase 3 trials are global

In that regard, we note the importance of expanded access programmes (EAPs), which provide access to novel treatments

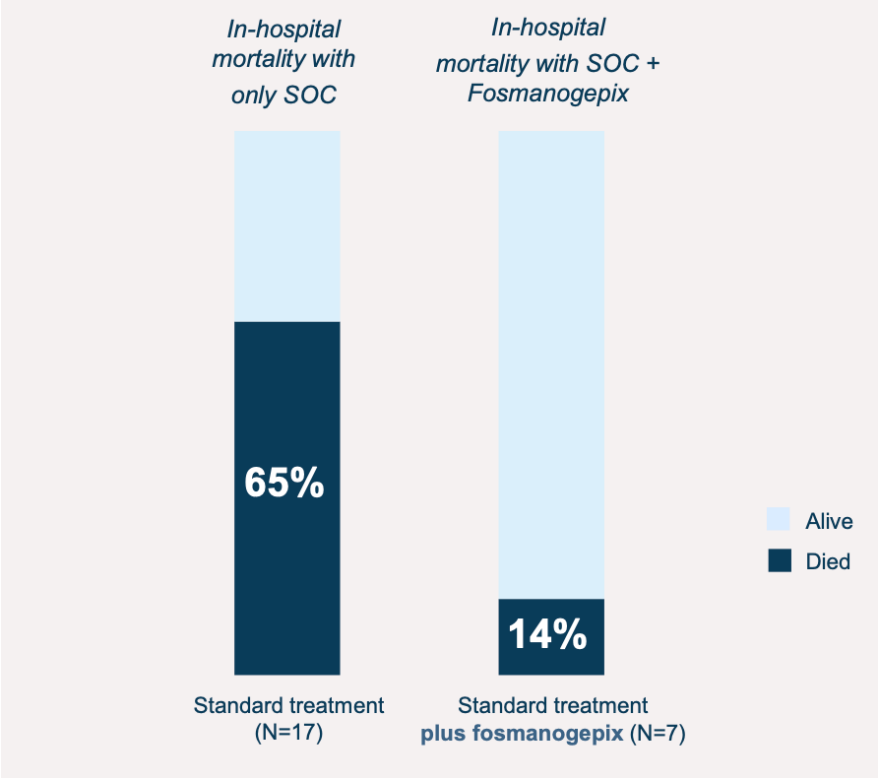
Potential for early access given recent real-world data

ahead of approval in that geography. Basilea provides Expanded Access to fosmanogepix through an agreement with the CRO WEP Clinical.

Data are compelling

Supporting the use of fosmanogepix as part of an EAP are the data already generated in the clinical programme, as well as the February 2024 report in NEJM of its successful compassionate use in immunocompetent patients as part of an outbreak of *Fusarium solani* meningitis at two clinics in Mexico, among patients who received epidural anaesthesia. Of the thirteen patients identified in the article (from a Texas hospital) and treated with existing antifungal agents, nine died, while three out of four who received fosmanogepix survived. Additional (postmortem) analysis showed that the fungus causing the outbreak was resistant to all available antifungals except fosmanogepix. Notably, the brain stem (vertebrobasilar system) was involved, suggesting that fosmanogepix's excellent tissue penetration may have contributed to the successful outcome. Although these are small numbers, nosocomial fungal infections have been observed in several instances. Given that the source of the infection has not been confirmed, it is possible that similar infections could still occur, especially where medical tourism is involved.

Fusarium meningitis outbreak in US/Mexico



Source: Basilea investor presentation

Expect more EAPs to confirm the attractive profile

Given the high-profile nature of the abovementioned cure for patients with life-threatening *Fusarium* infections (where other antifungals have failed), fosmanogepix may well be used as part of other EAPs. Basilea has reported that it has been used in over 300 patients across more than 10 countries, treating infections including aspergillosis and *Candida* infections, as well as invasive fusariosis

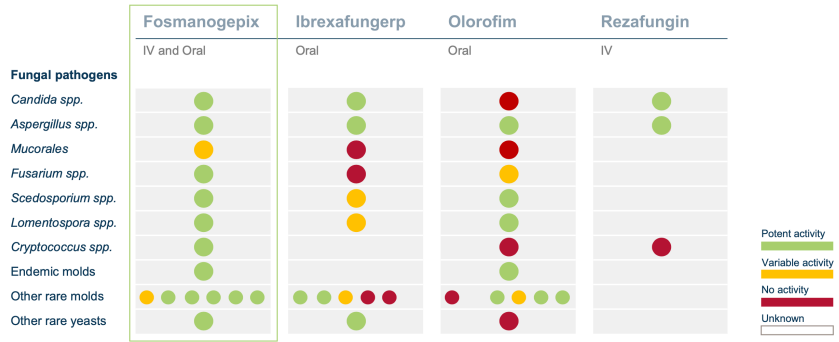
and rare but life-threatening moulds. Data were also presented at ESCMID Global 2025, which showed that treatment of patients with invasive fusarium and mucormycosis with fosmanogepix experienced a highly credible response rate of 70% or higher and was well tolerated. Further data generated from Expanded Access could help provide some insight into fosmanogepix's commercial potential and help save lives, particularly where existing treatments have been exhausted or where no suitable alternative is available. It is also worth noting that the invasive moulds trial is an open-label design. As a result, there may be an opportunity to provide an update on its progress without compromising the quality of the data readout at the primary endpoint.

New antifungals in development

The acquisition of fosmanogepix has been timely. Not only is Cresemba advancing towards maturity in the major markets of the US and Europe, but the competitive environment is also intensifying with several novel antifungals in clinical development. Nevertheless, we believe that the profile of fosmanogepix suggests that it has a highly competitive profile.

Fosmanogepix's favourable profile

Fosmanogepix has a highly relevant profile



Source: Basilea investor presentation

Full pipeline of antifungals in development

The above diagram demonstrates the excellent applicability of fosmanogepix to a broad range of important fungal infections. While the competitive environment surrounding *Candida* and *Aspergillus* may be more intense, the schematic does not include other important differentiating features which favour fosmanogepix. Nevertheless, it is encouraging and reassuring to see that a relatively full pipeline of novel antifungal agents is progressing through clinical development. While olorofim may have been undone by following a limited population pathway, we are heartened to see that rezafungin was approved on the back of a relatively small Phase 3 study (with a generous 20% non-inferiority margin).

Upon closer examination of the competitive environment, we have previously highlighted the checkered development of olorofim. Olorofim is a member of the ortomide antifungal class targeting fungal dihydroorotate dehydrogenase (DHODH), which is involved in pyrimidine synthesis. Although not a broad-spectrum antifungal, it has broad microbiologic activity against several important invasive moulds. Available orally, olorofim has been awarded FDA

Breakthrough Therapy Designation for the treatment of invasive fungal infections in patients with limited or no treatment options, including aspergillosis refractory or intolerant to currently available therapy, and infections due to *Lomentospora prolificans*, *Scedosporium*, and *Scopulariopsis* species, as well as treatment of patients with coccidioidomycosis refractory to standard of care.

New funding secured

In May 2022, the originator, F2G, received $100 million in upfront payments, with the potential to receive up to a further $380 million in regulatory and commercial milestones, as well as double-digit sales royalties from its commercial partner, Shionogi. However, olorofim received a complete response letter from FDA in June 2023 following its application for approval with a proposed label for the treatment of invasive fungal infections in patients with limited or no treatment options. More recently, the outlook for the progression of olorofim took a significant step forward with the announcement that F2G had raised $100m to fund additional Phase 3 evaluation.

Fungerp class promising

Ibrexafungerp (SCY-078) represents the first of a new class of "*fungerps*". It may share the same target as the echinocandins but targets a different binding site in the fungal cell wall (a derivative of enfumafungin). Its mode of action increases the permeability of the fungal cell wall, ultimately resulting in cell death.

Phase 3 MARIO study re-starting

Ibrexafungerp displays fungistatic activity against *Aspergillus* and fungicidal activity against *Candida* but lacks reliable activity against *Fusarium* or *Mucorales*. Given a general lack of cross-resistance with the echinocandins and its availability as an oral presentation, there is the potential for ibrexafungerp to be used as an oral step-down therapy to injectable echinocandins in the short term. We note that the Phase 3 study (MARIO) with ibrexafungerp as a step-down therapy in the treatment of invasive candidiasis has restarted (May 2025) following an earlier clinical hold. We further note that Scynexis and its partner, GSK, appear to be in dispute regarding the MARIO study.

SCY-247 a 2nd generation fungerp

The antifungal pipeline at Scynexis also features its second-generation "fungerp" SCY-247. SCY-247 appears to have potent activity against a broad range of fungal infections, including multi-drug-resistant strains, such as azole-resistant *Candida* and *Aspergillus* spp. If successful, SCY-247 could capitalise on the use of the echinocandins as first-line treatment options in invasive fungal infections caused by *Candida* and *Aspergillus*. SCY-247 exhibits activity against resistant strains and appears more potent (with greater bactericidal activity) than ibrexafungerp against resistant strains of *C. auris.* It also offers both IV and oral preparations.

Now in Phase 1

While the profile of SCY-247 appears promising, it is still in the early stages of development. SCY-247 entered Phase I trials in December 2024. This is a randomised, double-blind, placebo-controlled study targeting the 8olymyxin of around 100 healthy volunteers.

Rezafungin rounds out the near-term competitive environment. Rezzayo (rezafungin) is a novel echinocandin (derived from anidulafungin). Its main differentiating features include a longer half-

Rezzayo, a novel echinocandin

life, allowing for once-weekly intravenous dosing, a better volume of distribution, and activity against biofilms and azole-resistant *Candida,* including *C. auris* and *N. glabrata.* The pharmacokinetic profile of rezafungin facilitates a front-loading dosing regimen with a higher loading dose administered. This regimen results in high exposure early in patient treatment, resulting in increased fungal killing. Rezafungin should benefit from the echinocandins' position in guidelines as first-line treatment, and its once-weekly dosing should facilitate outpatient treatment, potentially removing the need for a central venous line. Rezafungin also offers greater stability than other echinocandins and represents a significant advance over existing members of the class.

Approved following a small Phase 3

Rezafungin was approved in the US in March 2023 for the treatment of adults with candidemia and/or invasive candidiasis who have limited or no alternative treatment options. European and UK approval was secured in late 2023/early 2024. Approval was based on a single Phase 3 trial where rezafungin was compared to caspofungin (followed by oral step-down therapy). The primary endpoint was 30-day all-cause mortality using a 20% non-inferiority margin.

Fosmanogepix has multiple differentiating features

Considering the competitive environment, it is tempting to conclude that if successfully developed, fosmanogepix offers a broader spectrum, encompassing most of the WHO-listed critical fungal infections. Importantly, its excellent penetration of tissues and organs, such as the CNS and eye, where other antifungal approaches are deemed insufficient, promises a significant differentiation. It also offers the potential for oral step-down therapy, which could be a meaningful differentiator given that it's the same treatment. In contrast, oral step-down therapy in invasive candidiasis with an echinocandin usually involves moving to azole-based treatment.

BAL2062 – a differentiated approach

Attractive positioning for BAL2062

BAL2062 is the first of a new class of siderophore-like hexapeptide antifungal agents. BAL2062 is differentiated by its novel mechanism of action that includes rapid fungicidal activity, with data generated to date suggesting activity against a range of difficult-to-treat fungal pathogens (including azole-resistant strains). The rapid reduction in fungal burden, along with a lack of cross-resistance to existing antifungal classes (such as the azoles), could be highly attractive features of BAL2062.

Good safety profile likely

BAL2062 originated at Astellas and is a naturally derived cyclic hexapeptide from the Malaysian leaf litter fungus. Its mechanism of action is based on the use by fungi (and other pathogens) of the siderophore ferrichrome. Fungi require ferrichrome to scavenge for essential iron when levels are low. Importantly, it is transported in fungal cells by the Sit1 transporter. Fortunately, since human cells do not possess a Sit1 transporter, BAL2062 is expected to have minimal toxicity.

IA the principal target

Although the principal commercial target is likely to be invasive aspergillus infections, including azole-resistant, BAL2062 also has activity against other important fungal pathogens, including *N. glabrata* and *Fusarium solani*.

Phase 2 progression is critical

BAL2062 is still in its early stages of clinical development, with Phase 1 clinical evaluation demonstrating its safety and tolerability. BAL2062 also benefits from QIDP and Fast Track designations for IA. Basilea intends to commence Phase 2 trials in 2026. The addition of BARDA funding under the existing OTA should help accelerate development if BAL2062's attractive profile warrants further development.

IST now in launch mode for Zevtera in the US

SAB indication is the key

As a 5th-generation cephalosporin antibiotic with anti-MRSA activity, the commercial appeal of Zevtera (ceftobiprole) may initially appear limited. However, there remains a clear need for an anti-MRSA antibiotic, particularly in the treatment of bacteraemia caused by *Staphylococcus aureus*. We believe that the SAB indication is key to Zevtera's future commercial success. This is a substantial opportunity with circa 120,000 SAB patients in the US per year, of whom approximately half involve infection with MRSA. With only vancomycin and daptomycin approved for SAB and with a growing threat of emerging resistance, there is a clear need for new treatment alternatives, particularly one with the known safety and tolerability profile associated with the cephalosporin class.

Considerable practice variation in SAB currently

Even in the key SAB indication, it will be interesting to see how ceftobiprole is used in the absence of up-to-date treatment guidelines. There appears to be considerable practice variation in the treatment of SAB, perhaps reflecting the lack of treatment options and compelling clinical data from well-controlled trials (until now). Treatment with a beta-lactam antibiotic remains first line for patients with susceptible infections (MSSA), which can last up to six weeks if the condition has become metastatic, compared to two weeks if the bacteraemia remains uncomplicated. Antibiotics typically used for MSSA include anti-*Staphylococcal* penicillins such as flucloxacillin and first-generation cephalosporins such as cefazolin.

Anti-MRSA activity

Patients with confirmed and suspected MRSA, as well as in institutions where resistance is a concern, look to be the initial unmet need for Zevtera. MRSA inevitably leads to poorer outcomes, with 15%-50% mortality rates in patients with MRSA bacteraemia. The glycopeptides, vancomycin and daptomycin, are first-line treatments in MRSA bacteraemia, requiring 4-6 weeks of intravenous therapy. Metastatic infections often require surgical intervention and can result in extended hospitalisation.

Limited alternatives

Although still relatively rare, there is a growing risk of resistance to both vancomycin and daptomycin. As a result, the lipoglycopeptide dalbavancin may be used (currently off-label) as an alternative to vancomycin-resistant infections and has the added benefit of offering a lower level of renal injury in comparison and a long half-

life, resulting in a much-reduced dosing schedule. Dalbavancin offers the potential for a shorter and less invasive treatment regimen, lowering risks associated with prolonged central venous access.

Still looking for effective alternatives

The standard of care (vancomycin and daptomycin) has been associated with a significant risk of treatment failure. Furthermore, vancomycin has poor tissue distribution and a risk of renal toxicity. Additionally, daptomycin is inactivated in the lungs, rendering it ineffective for the treatment of respiratory infections. Ultimately, we believe there is a clear need for additional antibiotics in SAB with a notable shortage of high-quality controlled studies. Previously, salvage therapy using an unapproved (off-label) antibiotic (such as the 5th generation cephalosporin ceftaroline) has proven to be a last resort approach in those with a persistent infection.

Clear need and market potential for Zevtera

The attraction of Innoviva Specialty Therapeutics (IST) brings a committed partner for the US commercialisation of Zevtera. We believe there are several reasons why the attraction of IST represents a committed partner, which should help maximise Zevtera's peak sales potential. The current anti-infective portfolio at IST comprises several hospital-based complementary antibiotics targeting important infectious diseases. Although Zevtera, as a 5th-generation cephalosporin, may not represent a transformative approach, considering the long-term availability of other similar treatments, such as ceftaroline, it is the only cephalosporin to have a specific approval for *Staphylococcus aureus* bacteraemia (SAB). IST has clearly recognised the need and market potential associated with the SAB opportunity, and we look forward to feedback post-launch. Previously, we modelled ceftobiprole to achieve a 10-12% peak penetration of the US bacteraemia market, resulting in a peak sales opportunity of $250m. Patients with SAB typically receive antibiotics for a duration of 2 to 6 weeks. Additionally, we have assumed that ceftobiprole can secure a modest 2-3% share of the large ABSSSI market at peak, recognising that this is a much more competitive area with other more entrenched competitors (e.g. ceftaroline). Nevertheless, given the size of the ABSSSI indication in the US, even this modest market penetration suggests a peak sales market potential of $130 million, and we also have the CABP indication to consider. Overall, we forecast that ceftobiprole could achieve peak in-market sales of approximately $380 million in the US.

DOTS positive for dalbavancin

The launch of ceftobiprole coincides with the publication of the Phase 2b DOTS (dalbavancin as an option for treating SAB) study in the August issue of JAMA. As noted above, dalbavancin has been used off-label for the treatment of complicated SAB, with the results first presented at ESCMID in April 2024. Although dalbavancin did not meet the primary endpoint of superiority to standard of care as measured by the highly relevant (for dalbavancin) desirability of outcome ranking (DOOR), which looked at a combination of clinical success, infectious complications, safety complications, mortality and health related quality of life, it did meet the secondary outcome of non-inferiority to standard of care with respect to overall clinical success. The formal publication of DOTS in a prestigious journal

should help raise awareness of the importance of new and alternative approaches to treating SAB, particularly as they relate to achieving better outcomes.

Beta-lactamase combination expanding late-stage pipeline

Gram-negative infections are a significant unmet need

The major unmet need in bacterial infections has been the treatment of problematic infections caused by Gram-negative bacteria. For the anti-bacterial franchise to extend beyond ceftobiprole, targeting Gram-negative infections represents a significant unmet need and an important objective for Basilea. Gram-negative infections are generally more challenging to treat than Gram-positive infections due to the outer membrane, which effectively blocks certain antibiotic classes.

WHO list of priority pathogens

Resistance associated with Gram-negative infections is therefore particularly concerning, with few treatment options available and little progress. Such is the seriousness of AMR that the WHO has published a list of priority pathogens, the majority of which are Gram-negative. The list is divided into three priorities based on their risk to human life. The highest-level Priority 1 pathogens are all Gram-negative and are deemed to pose a critical threat and comprise *Acinetobacter baumannii*, *Pseudomonas aeruginosa* and *Enterobacteriaceae,* where resistance has become a significant problem.

Focus on *Enterobacteriaceae*

Basilea has recently announced the addition of the ceftibuten-ledaborbactam etzadroxil combination. Ceftibuten is an orally available 3rd generation cephalosporin antibiotic approved as Cedax for susceptible strains of bacteria, including *Moraxella catarrhalis* (including beta-lactamase producing strains), *Haemophilus influenzae* (including beta-lactamase producing strains) and *Streptococcus pneumoniae* as they relate to acute bacterial exacerbations of chronic bronchitis, acute bacterial otitis media, and pharyngitis/tonsilitis caused by *Streptococcus pyogenes*. Ledaborbactam etzadroxil is a novel, broad-spectrum boronic acid beta-lactamase inhibitor.

Targeting cUTIs

The intention is to develop the combination as an oral therapy for the treatment of cUTIs caused by Enterobacterales. Enterobacterales remain the principal cause of most uncomplicated and complicated UTIs, with cystitis, for example, a common reason for prescribing antibiotics, generally with beta-lactam antibiotics, the favoured first-line treatment option given their benign profile and potent bactericidal activity. Unsurprisingly, as a result of widespread prescribing for various indications, resistance has become a significant issue. The combination has been granted QIDP and Fast Track designations by the FDA for cUTI as well as uncomplicated UTI (uUTI).

Growing resistance is a real issue

UTIs caused by extended-spectrum beta-lactamase-producing Enterobacterales have become a growing issue in many countries, with resistance to fluoroquinolones as well as oral beta-lactams such as cephalosporins and amoxicillin-clavulanate, highlighting

the need for new treatment options. Oral fluoroquinolones, for example, are no longer recommended as empiric therapy for cystitis given the threat of increasing resistance. Moreover, patients with pyelonephritis (kidney damage) have few treatment options, given growing concerns over resistance to oral fluoroquinolones.

Potential as an oral step-down therapy reducing hospital stay and costs

First line empiric therapy of cUTI as per IDSA guidelines suggests the use of 3rd or 4th generation IV cephalosporins, and that where an oral route of treatment is suitable, the fluoroquinolones or trimethoprim-sulfamethoxazole is appropriate or as an alternative to oral cephalosporins. The oral activity of the ceftibuten-laborbactam combination should therefore be appropriate for cUTI patients as an oral step-down therapy for those who have completed several days of intravenous therapy.

Tried and tested approach

This programme follows the same tried and tested route to reverse the resistance to other beta-lactam antibiotics, including ceftazidime-avibactam (Avicaz/Zavicefta), imipenem-relebactem (Recarbrio), meropenem-vaborbactam (Vabomere), and ceftolozane-tazobactam (Zerbaxa).

Avycaz is a good indicator

The success of Avycaz in particular portends well for the potential future commercial success of ceftibuten-ledaborbactam, we believe. Avycaz is a combination of the 3rd generation cephalosporin ceftazidime and a novel beta-lactamase inhibitor. Ceftazidime was chosen at the time, given its broad beta-lactamase spectrum, making it a better treatment option for multidrug-resistant bacteria. Avycaz was approved in 2015 for complicated intra-abdominal infections (cIAI) and in 2017 for cUTI (including pyelonephritis) caused by susceptible Gram-negative bacteria, including *Enterobacteriaceae* and *P.aeruginosa*. The third approval for HAP/VAP was provided in 2018. Avycaz generated sales of $659 million in 2024. While clearly benefiting from a broader label than ceftibuten-laborbactam, the latter has the benefit of being an oral preparation, offering outpatient and oral step-down treatment options for cUTI patients. According to the CDC, there are approximately 3 million patients in the US every year suffering from a cUTI, with 600,000 hospitalisations, the majority of whom are female. With an approximate cost of $7500-$15000 for 7/14 days of treatment, even a modest 10% share of the hospitalised market suggests peak sales of $450m in the US alone. It is also worth noting that there are approximately 250,000 patients with pyelonephritis in the US, confirming the magnitude of the current unmet need.

Susceptibility data positive, confirming activity and required profile

Given the scale of the unmet need and the size of the opportunity, efforts are ongoing to develop new oral approaches to treat cUTIs, in addition to the ceftibuten-ledaborbactam combination. That said, there have also been notable failures with eravacycline, in particular a once heavily touted new approach, failing to show non-inferiority to ertapenem. More positively, GSK intends to file for approval of the oral carbapenem tebipenem HBr for the treatment of cUTIs in H2 2025 following the positive outcome of the Phase 3 PIVOT-PO study. If approved, tebipenem would represent the first approval of

an oral carbapenem for the treatment of cUTI in the US. Although tebipenem should be the first to market, we note that as a new entrant from an existing class, there is a potential concern that class-specific cross-resistance may emerge over time, suggesting a need for multiple treatment options. Moreover, ceftibuten-ledaborbactam may also offer the potential benefit of a lower pill burden and less frequent dosing (OD) than tebipenem (2x 300mg every six hours) and a differentiated microbiological profile (no reduced activity against carbapenem-resistant *Enterobacteriaceae*), suggesting that it should offer a highly relevant addition, despite the expected availability of tebipenem.

A validated Phase 3-ready programme

We have described ceftibuten-ledaborbactam as a validated programme based mainly on the preclinical data during its tenure at originator Venatorx. Several studies have examined and compared the activity of ceftibuten-ledaborbactam against relevant *Enterobacteriaceae* clinical isolates, including non-susceptible clinical isolates. In the most recent study, ceftibuten-ledaborbactam was tested against a large number (3889) of relevant (recent and global isolates), which included those with extended beta-lactamase activity, multidrug resistance and other non-susceptible organisms. Given the mix of different (and difficult to treat) isolates tested and the anticipated activity of ledaborbactam, the study confirmed the ability of the combination to restore ceftibuten activity with susceptibilities similar to newer parenteral combinations (imipenem-relebactam), building on previous studies confirming similar activities to other newer parenteral beta-lactamase combinations such as ceftazidime-avibactam and meropenem-vaborbactam. For us, the result against multidrug-resistant isolates of almost 90% (89.7%) susceptibility was particularly impressive and compares well to 98.3% of isolates, which were presumed to have an extended beta-lactamase activity.

Additional non-dilutive funding from BARDA

With Phase I trials completed, confirming the safety and pharmacokinetics of the combination, Phase 3 trials are the next step. These trials are expected to begin within the next 18 months. Further cementing the importance of this programme has been the award of funding from BARDA, first to originator Venatorx and now transferred to Basilea. According to the contract, Basilea will receive an initial $6m with options to provide up to $153m on completion of predefined milestones.

BAL2420 – a novel Gram-negative candidate

Targeting *Enterobacterales* in a highly tailored approach

BAL2420 represents another programme targeting Gram-negative infections, but in a highly targeted fashion in line with current guidelines of antibiotic stewardship. It is, however, earlier in development than the ceftibuten-ledaborbactam combination and is yet to enter clinical trials.

Attractive profile

BAL2420 targets LptA with the objective of disrupting the outer membrane of Gram-negative bacteria by targeting the lipopolysaccharide (LPS) bridge. Given the outer membrane's importance in preserving the integrity of Gram-negative bacteria, targeting LPS production and its transport machinery has proven a productive approach in antibiotic drug development. Nevertheless, apart from the polymixins and colistin, which have significant limitations, efforts to develop direct inhibitors of LPS have been found wanting so far. Given the heightened risk of kidney damage associated with colistin and Polymyxin B, they are generally regarded as last-resort treatment options. The preclinical profile of BAL2420 appears to be very appealing as a potent inhibitor of LptA, exhibiting rapid bactericidal activity. Notably, it shows activity against *Enterobacteriaceae* strains (WHO Priority 1), including those resistant to beta-lactams and colistin.

CARB-X funding helpful

Despite its relatively early stage of development, we believe the award of non-dilutive funding from CARB-X is a significant endorsement of this approach, as CARB-X focuses on accelerating programmes targeting the WHO and CDC's priority pathogens list. CARB-X interest reflects the importance of LptA and BAL2420 as an exciting novel approach to targeting insidious and life-threatening infections caused by *Enterobacteriaceae*. We look forward to BAL2420 entering first-in-man studies, which are anticipated in mid-2026. BAL2420 is currently not included in our financial model or valuation of Basilea.

Risks

Basilea's business model currently involves partnerships and out-licensing to third parties, suggesting little influence over sales performance. Nevertheless, execution on key product Cresemba has been through highly appropriate partners (particularly Astellas and Pfizer), and we believe this model has worked well for Basilea and its partners. In particular, these are profitable relationships immediately post commercialisation without Basilea having to bear the significant costs required to launch a new product.

Fosmanogepix is key to the long-term future of the company's anti-infectives aspirations. The clinical data to date have been supportive and, with positive EAP results, suggest that the programme has been somewhat de-risked. However, Phase 3 clinical evaluation is ongoing, and we have used a 75% probability of success to reflect the remaining risk.

We believe IST will be a committed and effective commercial partner for Zevtera in the US. Given our expectations of sales success, we look forward to early launch feedback, particularly in the SAB indication.

The ceftibuten-ledaborbactam programme looks to be a validated addition with a good susceptibility profile, and as a result, we have introduced sales to our financial model, albeit with a 60% probability of approval. Development of new antibiotics for cUTI hasn't always been straightforward, and we look forward to details of the planned Phase 3 programme.

The LptA programme is both novel and early stage, suggesting that there is still a very real risk of failure. Therefore, we have not included BAL2420 in our financial model until more compelling data are generated. In any event, we expect Basilea to continue replenishing its pipeline with interesting programmes.

Financial Model and Summary

Excellent execution to date

Basilea's desire to become a global anti-infectives powerhouse has been significantly reinforced by the performance of the existing portfolio, the attraction of IST to commercialise Zevtera in the US and the recent addition of the Phase 3-ready combination ceftibuten-ledaborbactam. Equally important has been the company's ability to access non-dilutive funding. In particular, the award of a large multi-year OTA with BARDA has undoubtedly further enhanced Basilea's ambitions, providing funding (approximately 60% of development costs) and flexibility. We suspect that it has also highlighted the company's anti-infectives prowess to potential partners looking to add an experienced development partner in the complex anti-infectives field.

Antifungals dominate the anti-infectives pipeline

The company's success has been partly attributed to its primary focus on antifungals. Resistance is becoming a more significant issue, and there have been too few novel antifungal classes to provide effective alternatives. Notably, the introduction of a list of critical fungal infections by the WHO should stimulate interest, and Basilea stands to be a major beneficiary.

High-quality recurring growth

Financially, it is worth noting that Basilea remains a profitable company with a royalty stream consistently delivering double-digit growth, reflecting the high quality and recurring nature of Cresemba revenues. Moreover, despite the award of the OTA, Basilea already had the financial firepower to commit significant resources to completing the fosmanogepix Phase 3 programme.

Fosmanogepix is an exciting prospect

Of the above accomplishments, we remain particularly excited by the prospects for fosmanogepix. Given its profile and despite the intensifying competitive landscape, fosmanogepix has the potential to be an even larger commercial success than Cresemba. Fosmanogepix also holds promise in the context of IV to oral step-down therapy to provide outpatient treatment options. At the same time, its activity against most of the fungi on the WHO critical list suggests a broader label than Cresemba and should help maximise commercial success. Moreover, its activity against resistant strains and ability to penetrate important organs (particularly CNS) better than currently available antifungal classes should result in fosmanogepix featuring strongly in treatment guidelines.

Fosmanogepix's market potential is likely higher than Cresemba's

Based on successful Phase 2 results, we look forward to the completion of the Phase 3 programme for fosmanogepix now underway. In the interim, we look forward to updates from the ongoing expanded access programme, noting that with 300 patients already experiencing the lifesaving benefits of fosmanogepix before approval, there is the distinct possibility that more patients may have received fosmanogepix to treat challenging (often life-threatening) infections in a real-world setting than in the Phase 3 programme. These data should certainly provide comfort regarding the commercial applicability of fosmanogepix and hopefully result in an accelerated roll out once approved.

Filling the gap

Our forecasts suggest that fosmanogepix promises not only to continue the existing antifungal franchise established by Cresemba but also to extend the franchise into the treatment of candidiasis – a rapidly growing fungal threat. Along with our expectation that there should be a more expeditious global roll out than Cresemba's, our forecasts suggest peak sales of approximately $1.2 billion.

China and Japan will remain important markets for Cresemba post LoE

Our forecasts continue to assume that Cresemba sales will start to decline in both the US and Europe after the expiry of exclusivity in Q4 2027. Key to the longer-term outlook for Cresemba will be the recent launches in important markets, such as China and Japan, which represent substantial opportunities, accounting for approximately 18% of the overall global market. Both oral and IV preparations of Cresemba are now available in China. Although data for China are difficult to find, we note that there are significant growth drivers, including a marked increase in organ transplantation (particularly lung) in China in the recent past.

EAP data should further improve confidence in Phase 3 outturn

With fosmanogepix in Phase 3 development, it will not compensate for the lost Cresemba sales in 2028. However, we should have the Phase 3 data, which will provide further clarity on the long-term outlook for the anti-infectives franchise at Basilea. Before that, we expect confidence in the positive outcome of the Phase 3 programme to grow. Hopefully, additional EAPs will provide further insight into the potential of fosmanogepix in other needy treatment settings. The results of the fusarium patient subset published by NEJM are extremely gratifying and encourage continuing this endeavour where relevant. Additionally, we have highlighted the open-label nature of the Phase 3 trial in invasive moulds, suggesting the potential for de-risking as the trial progresses.

Expecting a rapid roll out of fosmanogepix post-approval

With Phase 3 trial data yet to come, we have risk-adjusted fosmanogepix sales with a probability of success of 75%. Given the Phase 2 data and the excellent EAP success, this approach seems conservative. Nevertheless, risks remain. Post-launch, we hope that, given the activity of fosmanogepix along with the global nature of the Phase 3 programme, fosmanogepix will enter markets outside the US and Europe on a timelier basis than Cresemba did.

Another component of growth is in place

The recent addition of the Phase 3 ceftibuten-ledoborbactam programme suggests another component of the growth story post-2028 is now in place. The Phase 3 programme is scheduled to begin in Q1 2027. Given the combination of positive Phase I and susceptibility data, we have introduced sales from 2029, albeit with a conservative 60% probability of success. It has been Basilea's model to license post Phase 3, and here we have assumed that the company will seek to maximise the longer-term value with no upfront and high teens royalties. At the same time, we have increased our 2027E and 2028E R&D forecasts to account for the Phase 3 programme, which is due to start in 2027. Hopefully, this is a conservative approach given the receipt of further funding from BARDA.

Zevtera's US launch is important

In the interim, we expect Zevtera's forthcoming US launch to help offset some of the predicted decline in Cresemba sales in 2028F. Our peak sales forecast of $380 million was based primarily on the

SAB indication and the company securing a commercial partner with relevant expertise. We believe that IST fulfils those requirements and note that recent corporate presentations have highlighted the importance of Zevtera as the first cephalosporin with a specific approval for SAB. This gives us comfort that IST is a committed partner with objectives for Zevtera that are aligned with those of Basilea.

Our forecasts include renewed guidance for 2025F and suggest a period of strong positive cash flow and sustainable profitability. Given the scale of operating loss carry forwards, we do not anticipate tax payments for the next several years. The addition of BARDA funding now offsets a significant portion of the R&D spend and will be received through other revenue streams. For now, however, we have not included sales from BAL2062 or BAL2420, as we suspect they are beyond our forecast time horizon in any case. Also, the timing of future milestone commitments as part of the fosmanogepix in-licensing has yet to be detailed. However, Basilea has been adept at managing costs while aggressively pursuing the creation of a world-leading anti-infective franchise.

Basilea Income Statement (CHF' 000)

Year to December	2023A	2024A	2025E	2026E	2027E	2028E
Total product and contract revenue		194865	189996	194625	197193	155349
Other revenue		13678	35000.0	38000.0	40000.0	42000.0
Total revenue	**157634**	**208543**	**224996**	**232625**	**237193**	**197349**
COGS	(26,794)	(38,681)	(38,249)	(41,872)	(42,695)	(35,523)
Gross profit	**130,840**	**169,862**	**186,746**	**190,752**	**194,498**	**161,826**
Gross margin	83.0%	81.5%	83.0%	82.0%	82.0%	82.0%
R&D	(77,852)	(77,143)	(104,623)	(111,660)	(113,852)	(106,568)
SG&A	(33,783)	(31,542)	(32,624)	(33,265)	(34,393)	(37,102)
Total cost and operating expenses	(138,429)	(147,366)	(175,497)	(186,798)	(190,940)	(179,193)
Non-underlying items	0.00	0.00	0.00	0.00	0.00	0.00
Operating profit US GAAP	**19,205**	**61,177**	**49,499**	**45,827**	**46,253**	**18,156**
Finance income	1,690	1,416	623	789	966	796
Finance expense	(11,202)	(4,344)	(3,836)	(3,279)	(1,650)	0
Other financial income	2,420	4,163	0	0	0	0
Other financial expense	(1,652)	(2,152)	0	0	0	0
Underlying PBT	10,461	60,260	46,285	43,336	45,568	18,952
PBT IFRS	10,461	60,260	46,285	43,336	45,568	18,952
Loss before tax	10,461	60,260	46,285	43,336	45,568	18,952
Tax	(10)	17,333	(5,091)	(4,767)	(5,012)	(2,085)
Underlying net income	**10,451**	**77,593**	**41,194**	**38,569**	**40,556**	**16,867**
Net income US GAAP	**10,451**	**77,593**	**41,194**	**38,569**	**40,556**	**16,867**
EPS Basic (CHF)	0.87	6.39	3.39	3.18	3.34	1.39
EPS Diluted (CHF)	**0.86**	**6.39**	**3.39**	**3.18**	**3.34**	**1.39**

Source: Calvine Partners Research

Basilea Cash Flow Statement (CHF' 000)

Year to December	2023A	2024A	2025E	2026E	2027E
Net profit/(loss)	10,451	77,593	41,194	38,569	40,556
Depreciation and amortization	1,577	1,732	775	815	859
Gain on disposal of assets, net	0	0	0	0	0
Stock-based compensation	4,762	5,066	5,319	5,585	5,865
Interest and accretion of debt issuance cost	1,443	600	534	534	0
Accounts receivable	5,229	19,025	6,650	(420)	(251)
Other receivables	(1,778)	(19,795)	3,532	(4,000)	(4,000)
Inventories	(2,166)	(5,199)	(5,875)	(1,271)	(761)
Accounts payable	5,656	5,640	2,013	(3,032)	206
Deferred revenue	(1,233)	(15,026)	(12,242)	(7,475)	0
Accruals and other current liabilities	(10,933)	7,395	7,395	7,395	7,395
Other operating cash flow items	1,235	(2,668)	0	0	
Net cash provided by/used in operating activities	**14,243**	**74,363**	**49,295**	**36,702**	**49,868**
Cash flow from investing activities					
Payments for short-term investments	0	0	0	0	0
Maturities of short-term investments	0	0	0	0	0
Payments for long-term investments	0	0	0	0	0
Proceeds from sale of assets	0	781	0	0	0
Investments in tangible assets	(813)	(1,710)	(802)	(882)	(970)
Investment in intangible assets	(221)	(82)	(374)	(374)	(374)
Net cash used in/provided by investing activities	**(1,034)**	**(1,011)**	**(1,176)**	**(1,256)**	**(1,344)**
Cash flow financing activities					
Net proceeds from exercise of stock options	(91)	(21)	(21)	(21)	0
Debt extinguishment	(59,314)	(15,603)	(14,918)	0	(82,517)
Issuance of Convertible bonds					
Senior secured loan					
Purchase of treasury shares	2,481	2,460			
Issuance of new shares	(381)	0			
Net cash provided by financing activities	**(57,305)**	**(13,164)**	**(14,939)**	**(21)**	**(82,517)**
Effect of exchange rate changes on cash and cash equivalents	(151)	50	0	0	0
Net change in cash and cash equivalents	(44,247)	60,238	33,180	35,425	(33,994)
Cash and cash equivalents at beginning of period	108,566	64,322	124,560	157,740	193,165
Cash and cash equivalents at end of period	**64,319**	**124,560**	**157,740**	**193,165**	**159,171**

Source: Calvine Partners Research

Basilea Balance Sheet (CHF' 000)

Year to December	2023A	2024A	2025E	2026E	2027E
Non-current assets					
Tangible assets, net	3,757	4,010	4,411	4,852	5,337
Intangible assets, net	548	374	374	374	374
Long-term investments	0	0	0	0	0
Deferred tax assets		17,333	12,242	7,475	
Other non-current assets	16,838	15,136	15,136	15,136	15,136
Total non-current assets	21,143	36,853	32,163	27,837	20,847
Current Assets					
Cash and cash equivalents	59,933	124,560	157,740	193,165	159,171
Short-term investments	0	0	0	0	0
Accounts receivable	27,891	8,876	12,375	12,794	13,046
Other receivables	30,257	49,306	49,306	49,306	49,306
Inventories	26,410	31,609	37,484	38,755	39,516
Other current assets	7,654	6,561	6,561	6,561	6,561
Total current assets	152,145	220,912	263,466	300,582	267,600
Total assets	**173,288**	**257,765**	**295,629**	**328,419**	**288,448**
Current liabilities					
Convertible senior unsecured bonds					
Senior secured debt	15,453				
Accounts payable	5,847	11,487	13,500	10,468	10,674
Deferred revenue	1,233	1,616	1,616	1,616	1,616
Accruals and other current liabilities	25,059	32,456	32,456	32,456	32,456
Total current liabilities	47,592	45,559	47,572	44,540	44,746
Non-current liabilities					
Convertible senior unsecured bonds	95,455	95,912	81,983	82,517	0
Deferred revenue, less of current portion	9,460	11,385	9,769	8,153	6,537
Senior secured debt					
Other non-current liabilities	30,784	23,910	23,910	23,910	28,910
Total non-current liabilities	135,699	131,207	115,662	114,580	35,447
Total liabilities	**183,291**	**176,766**	**163,234**	**159,120**	**80,193**
Shareholders equity (deficit)					
Share capital	13,100	13,170	13,170	13,170	13,170
Additional paid-in capital	1,042,002	1,047,567	1,047,567	1,047,567	1,047,567
Accumulated other comprehensive loss	(10,210)	(4,743)	0	0	0
Treasury shares held by a subsidiary	(54,008)	(51,702)	(51,702)	(51,702)	(51,702)
Loss carried forward	(1,011,337)	(1,000,886)	(923,293)	(876,185)	(837,616)
Net loss for the year	10,451	77,593	47,108	38,569	40,556
Total shareholders' equity (deficit)	(10,002)	80,999	132,850	171,419	211,975
Total liabilities and equity (deficit)	**173,289**	**257,765**	**296,084**	**330,540**	**292,168**

Source: Calvine Partners Research

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