# Calvine Partners



# Basilea Pharmaceutica

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# An important period for anti-infectives

Following a period in which Basilea invested in establishing a credible and relevant oncology pipeline, 2022 has brought a refocussing on the long-established anti-infectives franchise. In the near term, the franchise looks secure as the antifungal Cresemba (isavuconazole) continues to deliver highly creditable growth in existing markets through appropriate licensees. Notably, the longevity of the antifungals franchise was boosted recently by the in-licensing of a novel preclinical first-in-class antifungal programme, reflecting the continuing unmet need.

### Ceftobiprole rises again

Basilea was initially spun out from Roche as an anti-infectives focussed enterprise. While Cresemba has undoubtedly been a success, progress for the 5<sup>th</sup> generation anti-MRSA cephalosporin ceftobiprole has been less impressive to date. Although approved ex-US for the treatment of HAP/CAP, the lack of a VAP indication has been unhelpful, we believe, and as a result, sales of Zevtera (ceftobiprole) have been modest. However, this could be about to change. Following substantial investment by BARDA, ceftobiprole is on the cusp of delivering important data in the treatment of Staph. aureus bacteraemia (SAB). This remains a significant unmet need with only the glycopeptide antibiotics, vancomycin and daptomycin, approved by FDA for SAB involving MRSA. Both suffer from substantial limitations, including renal toxicity (vancomycin only) and emerging resistance. The ceftobiprole Phase 3 programme is well advanced with a positive TARGET study already concluded in severe skin infections. The remaining ERADICATE study is due to read out shortly, and previous data generated in SAB patients for ceftobiprole, as well as elsewhere, suggests reasons to be confident of a positive outcome. A positive result in both Phase 3 studies would meet the SPA requirements, which should reduce the regulatory risk with the FDA.

### 2023 profitability in our forecasts

According to our forecasts, continued growth from anti-infectives, combined with exiting oncology R&D, should drive Basilea to a sustainable cash flow positive position by 2023. The success of Cresemba is widely recognised thanks to its differentiated profile and the strength of its licensees in major markets. Underlying growth, even in mature markets, looks assured, and we look forward to the addition of other major territories to further boost growth. In the near-term, significant launches in China and Japan look promising. In this note, we highlight the potential for ceftobiprole - Basilea's 5th generation cephalosporin antibiotic, which is on the cusp of a US regulatory filing should the imminent result of the Phase 3 bacteraemia study prove positive. Success should result in the attraction of a suitable commercial partner and diversification of the anti-infectives franchise.

# Important transition period ahead

Following the decision to refocus on its anti-infectives franchise, the forthcoming result of the Phase 3 ERADICATE study for ceftobiprole now looms large. Ceftobiprole has been a constant feature at Basilea since its inception, and we look forward to a rejuvenation of its potential should ERADICATE deliver successfully. Following the positive result of the Phase 3 TARGET ABSSSI study in 2019 in severe skin infections, a positive impact from ceftobiprole in *Staph. aureus* bacteraemia would result in a regulatory filing. With a positive result from both ERADICATE and TARGET required to fulfil the requirements of the Special Protocol Assessment (SPA) and FDA approval, our analysis suggests that there are reasons to be sanguine regarding the prospects for ceftobiprole.

### Anti-infectives to the fore once again

The antifungal Cresemba (isavuconazole) has long dominated Basilea's anti-infectives franchise. Cresemba continues to outperform our already heady expectations thanks to strong underlying growth drivers (e.g. more aggressive chemotherapy regimens) and new geographies. Indeed, it has been Cresemba's success that has fuelled the investment behind the oncology pipeline and the opportunity to refocus on anti-infectives, accelerating Basilea's move to sustainable profitability.

### Can ceftobiprole be a significant revenue contributor?

The financial contribution from ceftobiprole (branded as Zevtera) has been modest to date. Sales are limited to ex-US (mostly Europe), and the European label is limited to CAP/HAP (excluding VAP). As Basilea has recognised, the US remains the key market for novel antibiotics, thanks in part to the high level of antimicrobial resistance and MRSA in particular. Within the nosocomial pneumonia opportunity, VAP is generally seen as the more urgent medical need where the presence of multidrug-resistant bacteria is associated with a significantly worse outcome and where 50% of antibiotic usage in the ICU lies.

As a 5<sup>th</sup> generation cephalosporin, ceftobiprole was designed with the increasing prevalence of MRSA in mind. It has an extended spectrum of activity against clinically important gram-positive bacteria, including MRSA, PRSP, and *Enterococcus faecalis*. Importantly, from an empiric therapy perspective, ceftobiprole also has activity against susceptible

ERADICATE is important for the antiinfectives refocus

Cresemba sales have been better than we anticipated

Current sales don't reflect the full potential of anti-infectives



Gram-negative pathogens, including *Citrobacter, Escherichia* coli, Enterobacter, Klebsiella, Serratia marcescens, and Pseudomonas aeruginosa. Despite its extended-spectrum and availability outside the US for many years, ceftobiprole has proven to possess a low propensity to develop resistance.

The US approval with a SAB label is key to success we believe

The role of the 5<sup>th</sup> generation cephalosporins is well established with ceftaroline in the treatment of severe skin infections and nosocomial pneumonia, also with ceftobiprole. However, we believe that the greater need lies in treating bacteraemia and sepsis caused by *Staph. aureus* (particularly where MRSA is suspected), and this is where ceftobiprole will be differentiated.

Bacteraemia is notoriously difficult to

Staph. aureus is the causative agent of several infections, which encompass skin and soft tissue infections and pneumonia. These infections can lead to the development of bacteraemia and infect distal sites and organs such as the heart, lungs and brain. Bacteraemia represents a particularly dangerous development, often leading to metastatic infections (such as infective endocarditis) and life-threatening complications such as sepsis. It often develops secondary to another site of infection (e.g. vascular catheter), but for a substantial proportion (c25%), the initial site of infection can't be identified.

Various risk factors

There are various risk factors for bacteraemia development, including a compromised immune system and respiratory disorders such as cystic fibrosis and emphysema, which increase the risk of complications. Moreover, risk factors for nosocomial infections include catheters (intravascular, urinary and feeding) and tubing used for dialysis and nutrition.

Complications suggest a poor prognosis

Over time, *Staph. aureus* has successfully developed various strategies to evade the human immune system. This includes forming biofilms which adhere to implantable devices. *Staph. aureus* biofilms are notoriously difficult to treat with current antibiotic-based strategies. In patients with SAB, complications such as endocarditis, abscesses, vertebral osteomyelitis and implanted device infections can develop several weeks or months after the initial infection.

The prevalence of SAB varies geographically, with developing countries significantly more affected than their first-world counterparts. In Europe, Southern European countries fare worse than those in the North, with 7 out of the 29 EU countries reporting that MRSA is found in 25% of *S. aureus* infections. In the key US market for ceftobiprole, the annual incidence of SAB is 38.2 – 42.7 per 100,000 person-years compared to between 10-30 per 100,000 years in the



developed world. This suggests a total SAB population of between 125,000 and 140,000.

Overall, bacteraemia is associated with a mortality rate of 20%. This rate has improved only modestly in the recent past despite efforts to better manage patients suffering from bacteraemia. Over 40% of *Staph. aureus* bloodstream infections in the US are caused by MRSA, justifying the development of antibiotics such as ceftobiprole in this important territory. The US is the target market for Basilea, and we believe that ceftobiprole, with its extended spectrum and potent activity against MRSA, will have high commercial appeal.

According to the CDC, 80% of MRSA bacteraemia events originate in the community, and while there has been significant progress in reducing hospital-onset MRSA bacteraemia, the rate of decline has slowed since 2012. On a more positive note, US Veterans Affairs centres have been able to reduce levels of MRSA by 55% and MSSA by 12%, thanks to implementing screening of new patients.

Also, we note that while hospital-acquired MRSA bloodstream infections have declined, thanks to the implementation of infection control procedures (such as decolonisation before high-risk surgery), the same cannot be said for community-acquired infections. The CDC noted that the apparent increase in SAB in the community was likely linked to the opioid crisis. Data from CDC suggest that SAB remains a significant concern, with 119,000 infections recorded in 2017, with almost 20,000 dying.

### Treatment choices for SAB limited

For patients with susceptible infections (MSSA), treatment with a beta-lactam antibiotic remains first choice, and if treatment guidelines are adhered to, can reduce the risk of mortality by as much as 50%. Treatment for SAB can be for up to six weeks if the infection has become metastatic compared to two weeks if the bacteraemia is deemed uncomplicated. Antibiotics typically used for MSSA include anti-Staphylococcal penicillins such as flucloxacillin as well as first-generation cephalosporins such as cefazolin.

While MSSA can be treated effectively, infection with MRSA leads to poorer outcomes, with up to 50% mortality in patients with MRSA bacteraemia. The glycopeptides vancomycin and daptomycin are used as first-line treatments in MRSA bacteraemia. However, although still relatively rare, there is a growing risk of resistance to both agents. The

The US is the target market

Infection reduction initiatives have reported success

More options for treating MSSA...

... less so MRSA



lipoglycopeptide dalbavancin may be used (off label) as an alternative to vancomycin-resistant infections. However, there are (largely theoretical) concerns that dalbavancin's long half-life could promote the emergence of resistance, not only to itself but also to related antibiotics such as vancomycin.

Dearth of clinical trials in SAB

Despite the availability of anti-MRSA cephalosporins such as ceftaroline and ceftobiprole, no Phase 3 controlled trials specifically targeting SAB patients have been concluded in SAB for any of the cephalosporin class. ERADICATE is set to be the first study to report which has evaluated the use of 5<sup>th</sup> generation cephalosporins specifically in SAB. We note that a Phase 2b study evaluating the use of dalbavancin for the treatment of SAB is ongoing. The long half-life of dalbavancin offers a significant dosing advantage over the glycopeptides, which require extended central venous access, although there are worries over resistance development.

Guidelines are outdated, but little has changed

IDSA guidelines have not been updated since 2011 despite an expectation to do so for some considerable time. However, as we have mentioned previously, we suspect that the surfeit of COVID-19 guidelines may have taken up valuable regulatory time. Nevertheless, little appears to have changed in the interim, with vancomycin the first-choice antibiotic for many. Daptomycin is also approved for SAB, and the prescribing label in the US includes approval for right-sided (but not left-sided) infective endocarditis (IE).

Current options have limitations

We have previously highlighted the limitations of daptomycin and vancomycin, which include emerging resistance (and the potential for cross-resistance) as well as vancomycin's poor tissue distribution and risk of renal toxicity. Additionally, daptomycin is inactivated in the lung, rendering it useless for the treatment of respiratory infections. Ultimately, there is a clear need for additional antibiotics in SAB with a notable shortage of high-quality controlled studies. Salvage therapy using a non-approved (off-label) antibiotic (such as dalbavancin and ceftaroline) has proven to be a last resort approach in those with a persistent infection.

Ceftaroline has SAB data on the label

The 5<sup>th</sup> generation antibiotic ceftaroline (branded as Teflaro) was granted a label expansion to include ABSSI patients suffering from concurrent bacteraemia. Ceftaroline was approved to treat patients with CAP and ABSSI in 2010. The label expansion was incorporated in 2015 based on patients in the two identical pivotal CANVAS 1 & 2 trials. CANVAS 1 & 2 compared ABSSI patients treated with ceftaroline to patients treated with vancomycin plus aztreonam. Of the 693 patients treated with ceftaroline, 20 patients had baseline SAB (nine of which were MRSA). 13/20 achieved clinical response



at Day 3, and 18/20 were considered clinical success at the Test of Cure (ToC). These data are included in the clinical trial section of the ceftaroline prescribing label.

Despite these encouraging results, there is no substitute for well-controlled, prospectively defined, clinical studies looking specifically at the target population (like ERADICATE), particularly with respect to optimal dosing and long-term treatment. Therefore, should ceftobiprole successfully complete the ERADICATE study, there is a significant opportunity in the treatment of SAB. As another 5<sup>th</sup> generation cephalosporin, ceftobiprole should be able to differentiate itself from ceftaroline with an approval and label that highlights not only ABSSSI but also SAB. Indeed, we suspect that success will provide ceftobiprole with a very strong position

for inclusion in relevant guidelines as they evolve.

In the Phase 3 ERADICATE study, ceftobiprole is being compared to daptomycin with the option to add aztreonam to provide coverage for Gram-negative pathogens if required. ERADICATE employs a non-inferiority (NI) design, with a generous non-inferiority margin of 15%. Daptomycin has been chosen as a relevant comparator given its activity in both MSSA and MRSA, while its approval in (right-sided) IE facilitates the double-blind design of ERADICATE.

Hospitalized male or female patients
 Age ≥19 years
 SAB, based on ≥1 positive blood culture obtained within 72 hours prior to randomization
 Signs or symptoms of bloodstroam infection
 Signs or symptoms of bloodstroam infection
 Sorread analyse value of complete the SAB, or definite native-value right-sided IE according to modified duke criteria
 Peogliroment for ≤26 (42)\* days of antibochrist treatment and the same of th

Source: Hamed, Engelhardt, Jones et al., Future Microbiology

The primary endpoint of ERADICATE is evaluating overall success at post-treatment evaluation (day 70 post-randomisation +/-5 days). Secondary endpoints include all-cause mortality and microbiological eradication. Basilea has sought to improve the positioning of ceftobiprole by extending the maximum treatment duration from four to six weeks. This extension allows ERADICATE to capture patients with more severe infections such as osteomyelitis and epidural/cerebral abscesses. ERADICATE is anticipated to read out in mid-2022.

Approval in SAB is important for future treatment guidelines

ERADICATE has a generous noninferiority margin

ERADICATE result is due soon



Forecasts suggest peak sales potential of \$250m in SAB

Preclinical data in SAB supportive

Positive clinical experience

...and real-world experience albeit with ceftaroline

Given the severity of SAB infection and challenges in treatment, we have apportioned a conservative 65% probability of success. With a positive outcome for both Phase 3 trials required as part of the Special Protocol Assessment (SPA), we have used this risk adjustment for both studies despite the already positive outcome of TARGET. Our forecasts suggest that ceftobiprole could achieve a 20% peak penetration of the US bacteraemia market, which would result in an un-risked peak sales opportunity of \$250m. Patients with SAB usually receive antibiotics for between 2-6 weeks. In our financial model, we have conservatively assumed that patients receive treatment for 5 weeks at \$6000 per treatment.

As we await the outcome of ERADICATE, it is important to note that preclinical data and emerging clinical data support the potential of ceftobiprole in the treatment of SAB. The preclinical data show rapid clearance of heart valve bacterial infections in models of aortic valve endocarditis and superior efficacy over vancomycin, linezolid and daptomycin.

There have also been case study data reported that demonstrated the activity of ceftobiprole in infective endocarditis patients (Tascini et al., JGAR 2020), albeit in combination with daptomycin (the comparator in ERADICATE). As resistance emerges to approved SAB antimicrobial therapy such as daptomycin, it is unsurprising, we believe, that physicians look to alternative approaches where ceftobiprole's activity against both MSSA and MRSA is desirable.

Of significant relevance, Basilea previously generated positive data from patients with bacteraemia in the four completed Phase 3 trials in ABSSSI, HAP/VAP and CAP. Although admittedly in a *post-hoc* analysis, 51 patients of the 3031 patients enrolled were found to have *Staph. aureus* bacteraemia. The conclusion was that ceftobiprole is associated with a similar clinical response to the comparators (vancomycin, vancomycin/ ceftazidime, and linezolid/ ceftazidime) with patients treated with ceftobiprole benefiting from a trend towards lower 30-day all-cause mortality.

Finally, we have also noted the label expansion of ceftaroline's prescribing data to include data in ABSSI patients concurrently infected with SAB. We believe these data provide an important additional source of real-world positive data regarding the 5<sup>th</sup> generation cephalosporin class. As a result, should ERADICATE be successful, ceftobiprole would be the only beta-lactam antibiotic specifically approved for SAB (including MRSA) with a fully characterised dosing schedule.



Significant upside to forecasts if positive...

...not just for SAB but also for ARSSI

In the US our peak sales forecast is circa \$400m for ceftobiprole

In their totality, we believe these data to be highly encouraging ahead of the read out from the completed ERADICATE study. Nevertheless, our forecasts incorporate a 65% probability of success to reflect the lingering risk, suggesting significant upside should the study be positive.

Additionally, the ABSSSI indication remains an important element of the regulatory filing process in the US, with both studies required for FDA approval. Ultimately, this is a large market, and our analysis suggests that even a small market share should generate meaningful revenues for ceftobiprole. A positive outcome for ERADICATE would also boost our ABSSSI forecasts through de-risking of the SPA requirement for two positive studies

For the ABSSSI indication, we believe that pricing will be similar to that achieved by other 5<sup>th</sup> generation cephalosporins. ABSSSI has a shorter course of treatment than SAB.

Although the ABSSSI indication has been de-risked with a positive TARGET study, we have employed the same probability of success as ERADICATE (65%) in our sales projections, given that a positive result from both studies is required for approval. We assume that ceftobiprole is able to secure a 3-4% share of the large ABSSSI market at peak, recognising that much will depend on the capabilities of the partner selected. Nevertheless, such is the size of the ABSSSI indication in the US, even this modest market penetration suggests an un-risked peak sales market potential of \$130m.



### **Risks**

Basilea has attracted strong and relevant commercial partners

Basilea's currently marketed products are out-licensed 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).

Lingering uncertainty in outcome of ERADICATE although supportive data exist

While the antibiotic Zevtera (ceftobiprole) is already marketed outside of the USA for the treatment of CAP and HAP (excluding VAP), we see the more significant market opportunity in the *Staph. aureus* bacteraemia (SAB) indication, particularly where MRSA is suspected. While data from previously completed studies which included SAB patients support this approach, there is uncertainty associated with this difficult-to-treat patient population, which is reflected in the probability adjustment we have employed. Approval of ceftobiprole in the US requires a positive outcome for both ABSSSI (already achieved) as well as the bacteraemia indication.

Partner(s) for oncology portfolio required

In February 2022, Basilea announced its decision to exit oncology R&D by the end of 2022, seeking transactions for its current clinical and preclinical oncology assets. We suspect that much will depend on the data readouts for derazantinib this year, particularly in gastric cancer. That said, the FGFRi class is well established, and there is broad applicability to a range of FGFR driven cancers. Additionally, Basilea has historically proven adept at securing relevant commercial partners.

Biomarker data important for lisavanbulin

Data on lisavanbulin may be in a small number of patients, but the effects have been positive in two patients with long-lasting clinical benefit. The relevance of the novel biomarker EB1 will be important in identifying appropriate patients in glioblastoma.

Refocusing brings forward profitability

Our financial forecasts suggest that this refocusing will result in Basilea moving towards a cash flow positive position in 2023 and sustainable profitability. With our expectation of a 2023 launch for ceftobiprole, our forecasts do not incorporate the expected upfront payment that the company would receive from a commercial partnership, suggesting some near-term financial upside.



Oncology is still important but will be progressed by partner(s)

Dependable growth from the antifungal franchise

Cresemba growth is forecast to continue

The addition of ceftobiprole should provide growth and longevity to the US franchise

### **Financial Model and Summary**

Until recently, the focus at Basilea had been to generate a meaningful and relevant oncology pipeline while progressing ceftobiprole through late-stage trials in the US. We believe that this effort has been successful to the extent that the company now has three clinical-stage oncology programmes. However, Basilea has taken the view that these assets will be better advanced by another party and has chosen to refocus on its already successful anti-infectives franchise. On reflection, and given the rapidly evolving competitive environment for the lead FGFRi programme, it is clear that it will take deep pockets to build a significant oncology franchise.

The anti-infectives franchise at Basilea continues to deliver good growth under the auspices of strong licensees in major markets. While the US market may be mature, growth appears assured with a combination of underlying growth and forthcoming approvals in major markets like China through licensee Pfizer as well as Japan through Asahi Kasei.

Our forecasts suggest that near-term growth should come from existing established markets through Astellas in the US and Pfizer elsewhere (Europe, China, Asia Pac, Russia, Turkey and Israel). One of the benefits of a lack of novel antifungals from new classes is limited competition, suggesting that the growth trajectory should continue.

Basilea's current overreliance on Cresemba is a nice problem to have given its current growth trajectory. However, initially approved in the US in 2015, Cresemba is maturing in initial launch markets while IP protection will wane from 2027 in the US. As a result, the potential addition of ceftobiprole in the US represents an important source of new revenues and additional growth. Although there is both a recognition of the need for new antibiotics and no shortage of apparent initiatives to pay for them, there appears to be a lack of willingness from the pharma majors to invest significantly in their development. On the plus side, we note that several alternative sources of funding are available with the Novo REPAIR fund, CARB-X, as well as financing through the PASTEUR Act in the US and the AMR Action Fund.

From Basilea's perspective, the availability of circa 70% of R&D funding for ceftobiprole from BARDA has represented an important source of non-dilutive financing. Additionally, ceftobiprole's award of QIDP status (as part of the GAIN Act) has provided 5 years of additional patent exclusivity. This



results in 10 years of exclusivity in the US, without which there would be no commercial reward.

Looking at the likely prescribing label in the US and potential market opportunity, our analysis suggests that it will be the SAB indication that should drive awareness of ceftobiprole's differentiated profile. The severe ABSSSI indication may be large but is congested with little differentiation over well-established alternative 5<sup>th</sup> generation antibiotics such as ceftaroline. However, we are hopeful that the perception of ceftobiprole will benefit from a positive ERADICATE result and a broader label than ceftaroline. The activity of ceftaroline in SAB in ABSSSI patients may be included in the clinical trials part of its prescribing label. However, the numbers were small, and this is a narrower claim than a general SAB indication.

Our financial model incorporates a 65% probability of success, with unrisked peak sales of circa \$400m in the USA alone. Despite recognising that Basilea will seek a commercial partner for ceftobiprole in the US, our financial model continues to include end-market sales and associated costs as we await details of any potential transaction. On the other hand, we have not included the impact of any upfront payment to Basilea. Elsewhere, a limited label likely hasn't helped European ceftobiprole (Zevtera) sales. Longer-term, there is potential to bring the US label to Europe, which could significantly boost Zevtera sales. This is beyond our current financial model.

2022 will likely be the year where there is a conclusion to the investment in the oncology franchise. During 2022, we look forward to various data points for derazantinib, particularly in the gastric cancer setting, which should further inform its differentiated nature in an increasingly crowded class. For lisavanbulin, we await the results from the ongoing biomarker-driven study in glioblastoma. Data so far have been supportive of this biomarker-driven approach.

Our forecasts suggest that the net result of this strategic refocus has been to reduce the expected R&D spend, particularly in 2023. With the urothelial cancer study essentially terminated, the remaining principal costs are related to the evaluation of derazantinib in gastric cancer (FIDES-03).

Our forecasts suggest that with its operational spend reduced in 2023, Basilea should move towards a positive cash flow and sustainable profitability, even without the benefit of any upfront payments, either from a strategic partner for ceftobiprole or any/all of the oncology pipeline.

The SAB indication should drive differentiation

European Zevtera sales could ultimately also reflect the SAB indication

2022 is likely to be the last year of R&D oncology investment

We forecast profitability from 2023



# Basilea Income Statement (CHF' 000)

Year to December	2019A	2020A	2021A	2022E	2023E	2024E	2025E
Total revenue	134381	127629	148122	110278	126314	133241	194060
cogs	(18,868)	(24,054)	(24,072)	(22,056)	(24,000)	(25,316)	(29,109)
Gross profit	115,513	103,575	124,050	88,223	102,314	107,925	164,951
Gross margin	86.0%	81.2%	83.7%	80.0%	81.0%	81.0%	85.0%
R&D	(102,662)	(97,410)	(93,157)	(81,606)	(50,526)	(51,964)	(64,428)
SG&A	(30,051)	(29,422)	(29,721)	(30,878)	(36,631)	(39,972)	(48,515)
Total cost and operating expenses	(151,581)	(150,886)	(146,950)	(134,540)	(111,156)	(117,252)	(142,052)
Non-underlying items	0.00	15,035	0.00	0.00	0.00	0.00	0.00
Operating profit US GAAP	(17,200)	(8,222)	1,187	(24,261)	15,158	15,989	52,008
Finance income	28	104	66	161	167	152	19
Finance expense	(6,424)	(7,589)	(8,151)	(6,784)	(3,353)	(3,353)	(3,353)
Other financial income	1,583	2,057	1,676	0	0	0	0
Other financial expense	(369)	(1,017)	(1,573)	0	0	0	0
Underlying PBT	(22,382)	(29,702)	(6,810)	(30,884)	11,972	12,789	48,675
PBT IFRS	(22,382)	(14,667)	(6,795)	(30,884)	11,972	12,789	48,675
Loss before tax	(22,382)	(29,702)	(6,810)	(30,884)	11,972	12,789	48,675
Tax	(40)	(55)	(37)	(60)	(1,700)	(1,816)	(6,912)
Underlying net income	(22,422)	(29,757)	(6,847)	(30,944)	10,272	10,973	41,763
Net income US GAAP	(22,422)	(14,722)	(6,832)	(30,944)	10,272	10,973	41,763
EPS Basic (CHF)	(2.09)	(1.43)	(0.67)	(2.74)	0.91	0.97	3.70
EPS Diluted (CHF)	(2.08)	(1.36)	(0.61)	(2.74)	0.91	0.97	3.70

Source: Calvine Partners Research



# Basilea Cash Flow Statement (CHF' 000)

	2019E	2020A	2021A	2022E	2023E	2024E
Net profit/(loss)	(22,422)	(14,722)	(6,831)	(30,944)	10,272	10,973
Depreciation and amortization	1,639	1,190	754	957	1,020	1,088
Gain on disposal of assets, net	0	(15,035)	(71)	0	0	0
Stock-based compensation	3,048	3,525	4,322	0	0	0
Interest and accretion of debt issuance cost	758	1,670	1,593	534	0	0
Accounts receivable	(2,457)	(1,657)	(16,251)	1,818	(882)	(381)
Other receivables	8,909	(1,657)	(15,813)	0	0	0
Inventories	(4,142)	(2,618)	(1,591)	7,904	(2,672)	(1,154)
Accounts payable	378	6,394	(2,538)	(611)	(1,311)	124
Deferred revenue	(45,626)	(33,630)	(2,556)	0	0	0
Accruals and other current liabilities	693	(1,425)	5,440	0	0	0
Other operating cash flow items	(4,614)	4,639	1,522	0	0	0
Net cash provided by/used in operating activities	(63,836)	(53,326)	(32,020)	(20,342)	6,427	10,650
Cash flow from investing activities						
Payments for short-term investments	(20,000)	(81,023)	(35,000)	0	0	0
Maturities of short-term investments	50,000	30,000	41,023	96,253	0	0
Payments for long-term investments	(30,000)	0	0	0	0	0
Proceeds from sale of assets	0	18,325	(1,588)	0	0	0
Investments in tangible assets	(294)	(1,823)	(581)	(1,249)	(1,374)	(1,512)
Investment in intangible assets	(110)	(442)	(279)	(332)	(332)	(332)
Net cash used in/provided by investing activities	(404)	(34,963)	3,575	94,671	(1,707)	(1,844)
Cash flow financing activities						
Net proceeds from exercise of stock options	37	1,322	1,866	0	0	0
Repayment of Convertible loan	0	(53,634)	(23,212)	(123,505)	0	0
Issuance of Convertible bonds	0	93,892	0			
Purchase of treasury shares	1,272	3,487	(4,254)			
Issuance of new shares			42,240			
Net cash provided by financing activities	1,309	45,067	16,640	(123,505)	0	0
Effect of exchange rate changes on cash and cash equivalents	67	(758)	501	0	0	0
Net change in cash and cash equivalents	(62,864)	(43,980)	(11,304)	(49,176)	4,721	8,806
Cash and cash equivalents at beginning of period	173,908	111,044	66,256	54,952	5,776	10,497
Cash and cash equivalents at end of period	111,044	67,064	54,952	5,776	10,497	19,303

Source: Calvine Partners Research



# Basilea Balance Sheet (CHF' 000)

Year to December	2019A	2020A	2021A	2022E	2023E	2024E
Non-current assets						
Tangible assets, net	5,162	2,627	2,018	6,871	7,558	8,313
Intangible assets, net	372	672	632	632	632	632
Long-term investments	30,000	0	2,390	0	0	0
Other non-current assets	1,073	2,967	1,161	1,161	1,161	1,161
Total non-current assets	36,607	6,266	6,201	8,664	9,351	10,106
Current Assets						
Cash and cash equivalents	109,024	60,749	53,700	5,776	10,497	19,303
Short-term investments	22,020	106,530	96,253	0	0	0
Accounts receivable	6,242	8,710	24,947	6,065	6,947	7,328
Other receivables	22,053	23,684	39,500	39,500	39,500	39,500
Inventories	18,569	21,192	22,783	18,372	21,044	22,198
Other current assets	6,952	2,663	3,883	3,883	3,883	3,883
Total current assets	184,860	223,528	241,066	73,597	81,871	92,212
Total assets	221,467	229,794	247,267	82,261	91,222	102,319
Current liabilities						
Convertible senior unsecured bonds			123,505			
Accounts payable	6,765	13,151	10,617	4,665	3,354	3,478
Deferred revenue	32,873	2,556	1,233	0	0	0
Accruals and other current liabilities	35,856	34,454	39,053	39,053	39,053	39,053
Total current liabilities	75,494	50,161	174,408	43,718	42,407	42,531
Non-current liabilities						
Convertible senior unsecured bonds	197,740	239,668	94,544	103,157	103,157	103,157
Deferred revenue, less of current portion	16,471	13,158	11,926	0	0	0
Other non-current liabilities	24,722	28,853	24,996	24,996	24,996	24,996
Total non-current liabilities	238,933	281,679	131,466	128,153	128,153	128,153
Total liabilities	314,427	331,840	305,874	171,871	170,560	170,684
Shareholders equity (deficit)						
Share capital	11,882	11,922	12,992	12,992	12,992	12,992
Additional paid-in capital	927,342	982,438	1,029,796	1,029,796	1,029,796	1,029,796
Accumulated other comprehensive loss	(24,555)	(27,252)	(21,617)	(21,617)	(21,617)	(21,617)
Treasury shares held by a subsidiary	(5,963)	(52,766)	(56,559)	(56,559)	(56,559)	(56,559)
Loss carried forward	(979,244)		(1,016,388)	(1,023,220)		(1,043,892)
Net loss for the year	(22,422)	(14,722)	(6,832)	(30,944)	10,272	10,973
Total shareholders' equity (deficit)	(92,960)	(102,046)	(58,608)	(89,552)	(79,280)	(68,307)
Total liabilities and equity (deficit)	221,467	229,794	247,266	82,319	91,280	102,377

Source: Calvine Partners Research



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