

Basilea Pharmaceutica

Funding update

BARDA backs Basilea's anti-infectives programme

Pharma and biotech

24 September 2024

Basilea has bagged a multi-year agreement with the Biomedical Advanced Research and Development Authority (BARDA), potentially worth US\$268m, to advance its anti-infectives franchise. The Other Transaction Agreement (OTA) will include an initial payment of US\$29m to support clinical development work for fosmanogepix and BAL2062 as they prepare to enter the next phase of clinical development. The agreement will last up to 12 years and management expects it to cover 60% of its development costs related to the covered programmes over the period. These expected inflows have triggered another guidance upgrade for FY24 (revenue of CHF203m, from CHF196m previously) with a significant uptick in the bottom line on increased deferred taxes (net profit guided to be CHF60m vs CHF42m previously). We have adjusted our estimates to reflect the potential non-dilutive funding from BARDA, with our valuation increasing to CHF95.3/share, from CHF89.7/share previously.

| Year end | Revenue (CHFm) | PBT* (CHFm) | EPS* (CHFc) | DPS (CHFc) | P/E (x) | Yield (%) |
|----------|----------------|-------------|-------------|------------|---------|-----------|
| 12/22 | 147.8 | 12.3 | 104.1 | 0.0 | 44.2 | N/A |
| 12/23 | 157.6 | 10.8 | 89.7 | 0.0 | 51.3 | N/A |
| 12/24e | 203.0 | 38.9 | 499.4 | 0.0 | 9.2 | N/A |
| 12/25e | 219.1 | 50.7 | 419.3 | 0.0 | 11.0 | N/A |

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Another dose of funding from BARDA...

Basilea's efforts towards building a pipeline of novel treatments for serious infections has received BARDA's support since 2013 (R&D funding for BAL30072 and more recently for Zevtera) and we believe this most recent funding reflects the continued strategic focus of the agency on this underserved market. The OTA includes options for up to US\$268m in funding covering a period of up to 12 years and allowing for BARDA and Basilea to jointly make decisions on portfolio candidates and churn. The initial US\$29m will focus on fosmanogepix (which has now initiated the first [Phase III study](#)) and BAL2062, and we expect Basilea to access these funds over a 15- to 18-month period (c US\$7m in reimbursement expected during FY24).

...De-risks Basilea's development programmes

Management estimates the US\$268m in R&D funding to cover c 60% of clinical costs over the course of the agreement, which should significantly de-risk ongoing and planned clinical programmes, comprising fosmanogepix, BAL2062 and the antibiotics tonabacase and LptA inhibitors. We note that the first Phase III clinical trial for fosmanogepix (in candidemia/invasive candidiasis) has now [commenced](#), with the second trial (in invasive mould infection) around year-end. We estimate Phase III trial costs for fosmanogepix to be US\$150m, with c 60% contributed by BARDA.

Valuation: CHF1,155.5m or CHF95.3 per share

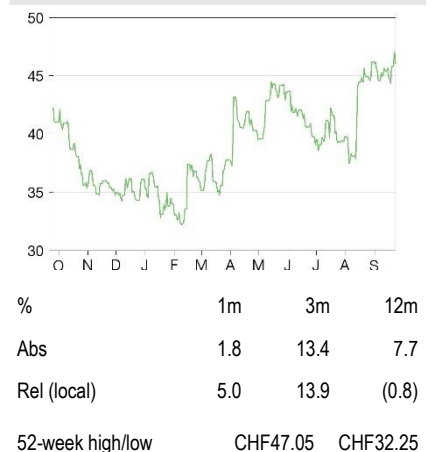
We adjust our estimates and valuation for fosmanogepix to reflect the BARDA reimbursement. Our projections do not currently include the preclinical programmes, and we note the potential upside as they enter the clinic, led by BAL2062 in 2025. We also upgrade our FY24 and FY25 estimates to factor in the revenue uplift from the BARDA funding. Our valuation rises to CHF1,155.5m or CHF95.3/share (from CHF1,087.2m or CHF89.7/share previously).

Price CHF46.0
Market cap CHF558m

US\$1.16/CHF

| | |
|---|-------|
| Net debt (CHFm) at 30 June 2024 | 26.2 |
| Shares in issue (excluding 1.12m treasury shares) | 12.1m |
| Free float | 90% |
| Code | BSLN |
| Primary exchange | SIX |
| Secondary exchange | N/A |

Share price performance



Business description

Basilea Pharmaceutica is focused on treating infectious diseases. Its marketed products are Cresemba (an antifungal) and Zevtera (an anti-MRSA broad-spectrum antibiotic). In late 2023, it expanded its clinical pipeline to include two antifungals, Phase III-ready, novel broad-spectrum antifungal treatment fosmanogepix (two Phase III trials to start in 2024) and Phase II asset BAL2062, and one antibiotic, tonabacase. In January 2024, Basilea acquired the preclinical LptA inhibitor antibiotics programme from Spexis.

Next events

| | |
|---|------|
| Announcement of US partner for Zevtera | H224 |
| Fosmanogepix Phase III initiation (candidemia/invasive candidiasis) | H224 |

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Non-dilutive BARDA funding to support growth plans...

BARDA has been spearheading the development of medical countermeasures and has previously supported Basilea's R&D efforts towards invasive and serious fungal and bacterial infections. In June 2013, the company signed its first contract with BARDA for up to US\$89m for clinical development of its Gram-negative antibiotic, BAL30072. While this programme was subsequently shelved (following completion of the Phase I clinical trial) the company recognised CHF13.5m in BARDA reimbursements between FY14 and FY15. Notably, BARDA had also provided funding for the Phase III development of Basilea's lead antibacterial candidate, Zevtera, which recently received US regulatory approval, with launch expected in the coming weeks, pending finalisation of the licensing partner. The contract for Zevtera was signed in April 2016, with BARDA providing funding of US\$111.9m, covering c 75% of Zevtera's development costs of c US\$150m. Moreover, CARB-X, a global non-profit partnership co-founded by BARDA, provided an initial grant of US\$0.9m to Basilea's preclinical LptA antibiotic programme in [April 2024](#).

The recent agreement structurally differs from the previous contracts, as it has been signed as an OTA, which allows for greater flexibility and oversight from BARDA, with both parties jointly able to make decisions on portfolio constituents and churn based on performance, risk and need. The agreement includes potentially US\$268m of non-dilutive funding to be provided to Basilea over up to 12 years, which management estimates will cover c 60% of its development costs over this period. We note, however, that it is conditional on BARDA exercising all additional options to extend the agreement, which will be contingent on the company meeting certain predefined clinical and regulatory milestones. However, the initial proceeds of US\$29m are committed towards R&D activities related to the Phase III asset fosmanogepix and BAL2062 (currently undergoing preclinical profiling, with the Phase II trial planned to initiate in 2025). We expect these initial funds to be provided/recognised over the next 15–18 months, with a majority directed towards fosmanogepix, which has now commenced the first Phase III trial in candidemia and invasive candidiasis (discussed below), with the second Phase III trial in invasive mould infections expected to start around year-end.

Driven by these expected receipts, management has upgraded its revenue guidance for FY24 from CHF196m to CHF203m, which indicates that CHF7m (US\$8.2m) of BARDA receipts will likely be recognised within FY24. While the operating expense guidance remains unchanged at c CHF120m, net profitability gets a leg up from additional deferred taxes recognised due to the expected medium-term impact of the OTA on Basilea's financial performance. The revised guidance is presented in Exhibit 1.

Exhibit 1: Revised company guidance

| CHFm | FY24 new guidance | FY24 previous guidance | FY23 |
|---------------------------------------|-------------------|------------------------|-------------|
| Cresemba- and Zevtera-related revenue | c 190 | c 190 | 150.3 |
| <i>Of which – royalty income</i> | <i>c 92</i> | <i>c 92</i> | <i>78.9</i> |
| Total revenue | c 203 | c 196 | 157.6 |
| Cost of products sold | c 40 | c 40 | 26.8 |
| Operating expenses | c 120 | c 120 | 111.7 |
| Operating profit | c 43 | c 36 | 19.2 |
| Net profit | c 60 | c 42 | 10.5 |

Source: Basilea press release, September 2024

...starting with first Phase III trial for fosmanogepix

The latest BARDA agreement was quickly followed by the announcement of the initiation of the [first Phase III trial](#) for fosmanogepix, a significant development given the strategic importance of the asset in Basilea's longer-term growth plans. Fosmanogepix is a first-in-class, broad-spectrum antifungal (including multidrug-resistant strains such as *Candida auris* and *Fusarium spp.*) with a novel mechanism of action, a key differentiator in the rise of antifungal drug resistance. The drug was acquired by Basilea in November 2023 from Amlyx Pharmaceuticals (for an upfront payment of US\$37m and potential milestone payments of US\$506m), an affiliate of Pfizer. It holds Fast Track and Orphan Drug designations from the FDA, as well as a qualified infectious disease product (QIDP) tag, providing regulatory and commercial benefits, as well as at least 12 years of market exclusivity post launch. Fosmanogepix, which is being developed in both oral and intravenous (IV) formulations, has shown activity against both yeast and moulds (including drug-resistant varieties) and is widely regarded as a potential successor to Cresemba (market exclusivity expiring in the US and Europe in late 2027), if clinical data are supportive.

The first Phase III registrational study (FAST-IC) will evaluate fosmanogepix against the standard of care (SoC) in the treatment of patients with candidemia and/or invasive candidiasis (yeast bloodstream or deep-seated tissue infections). The study is a global, multi-centre, randomised double-blind, active-controlled study, aiming to recruit c 450 patients, randomised 2:1 between fosmanogepix and the SoC caspofungin. The study is also designed to include an optional oral step-down (from the initial IV administration) in the fosmanogepix arm and to fluconazole in the caspofungin arm. As part of the deal terms agreed when acquiring fosmanogepix, Basilea will be required to make a milestone payment of US\$6m on enrolment of the first patient in the study. This payment is reflected in the FY24 financial guidance, according to management. As indicated earlier, we expect BARDA to reimburse c 60% of the fosmanogepix trial costs in addition to other development programmes over the agreement period.

Financials and valuation get an upgrade

We adjust our FY24 and FY25 estimates to reflect the expected inflows from BARDA. For FY24, we include CHF7m in BARDA reimbursement, to incorporate management guidance, and the remaining c CHF18m in FY25, assuming the entire US\$29m (c CHF25m) will be paid out by end-FY25. This results in our FY24 and FY25 revenue estimates increasing to CHF203.0m and CHF219.1m (from CHF196.0m and CHF201.6m), respectively. We keep our opex estimates unchanged, with the increase in operating income (FY24: CHF42.9m, FY25: CHF54.2m) almost entirely due to the increase in revenues. In line with management guidance, we increase our expectation of deferred taxes to CHF21.5m in FY24, resulting in net income of CHF60.1m versus CHF42.1m previously.

The primary change to our risk-adjusted net present valuation (rNPV) comes from the upgrades to our cash flow projections from the expected BARDA inflows for fosmanogepix, the only clinical-stage asset currently included in our valuation for Basilea. Cresemba and Zevtera are commercial products, and BAL2062 and tonabacase are currently undergoing preclinical studies and are hence excluded from our valuation. Our model estimates clinical trial costs of c US\$150m for fosmanogepix, which we previously assumed the company would fund from internally generated capital. We now project BARDA to fund c 60% of these costs (which translates to c US\$90m) between FY24 and FY29. This results in our rNPV for fosmanogepix increasing to CHF175.4m, from CHF118.3m previously, driving our overall valuation for Basilea to CHF1,155.5m or CHF95.3/share (from CHF1,087.2m or CHF89.7/share previously). Exhibit 2 presents a breakdown of our rNPV valuation of Basilea by asset.

Exhibit 2: Basilea Pharmaceutica valuation

| Product | Indication | Launch | Peak sales (\$m) | NPV (CHFm) | Probability | rNPV (CHFm) | rNPV/share (CHF) |
|----------------------------------|-----------------------------|--|------------------|----------------|-------------|----------------|------------------|
| Cresemba (isavuconazole) | Severe fungal infections | 2015 (US), 2016 (EU), 2018 (RoW), 2022 (China), 2023 (Japan) | 747 | 690.0 | 100% | 690.0 | 56.9 |
| Zevtera/Mabelio (ceftobiprole) | Severe bacterial infections | 2015 (EU), 2018 (RoW), 2025 (US) | 486 | 316.3 | 100% | 316.3 | 26.1 |
| Fosmanogepix | Severe fungal infections | 2029 (US, EU and Japan), 2030 (RoW) | 801 | 316.0 | 60% | 175.4 | 14.5 |
| Net cash/(debt) at end June 2024 | | | | (26.2) | 100% | (26.2) | (2.2) |
| Valuation | | | | 1,296.1 | | 1,155.5 | 95.3 |

Source: Edison Investment Research

Note that our valuation currently does not account for other early-stage programmes (BAL2062 and tonabacase) or the potential BARDA reimbursements for these assets, which may lead to additional upside as these assets move into the clinic.

Exhibit 3: Financial summary

| Accounts: US GAAP, year-end: 31 December, CHF'000s | 2021 | 2022 | 2023 | 2024e | 2025e |
|--|----------|----------|----------|----------|----------|
| PROFIT & LOSS | | | | | |
| Total revenues | 148,122 | 147,765 | 157,634 | 203,042 | 219,055 |
| Product revenues (Cresemba and Zevtera) | 131,382 | 122,315 | 150,275 | 190,242 | 195,823 |
| Cost of sales | (24,072) | (24,603) | (26,794) | (40,041) | (34,616) |
| Gross profit | 124,050 | 123,162 | 130,840 | 163,001 | 184,439 |
| Research and development expenses (net) | (93,157) | (73,804) | (77,852) | (84,869) | (92,343) |
| SG&A costs | (29,721) | (30,815) | (33,783) | (35,208) | (37,919) |
| Exceptionals and adjustments | 15 | 0 | 0 | 0 | 0 |
| EBITDA (reported) | 1,941 | 19,640 | 20,782 | 44,130 | 55,462 |
| Reported operating income | 1,187 | 18,543 | 19,205 | 42,924 | 54,178 |
| Operating margin % | n/a | n/a | n/a | n/a | n/a |
| Finance income/(expense) | (7,982) | (6,441) | (8,744) | (4,356) | (3,803) |
| Profit before tax (reported) | (6,795) | 12,102 | 10,461 | 38,568 | 50,375 |
| Profit before tax (normalised) | (6,610) | 12,302 | 10,761 | 38,859 | 50,678 |
| Income tax expense (includes exceptionals) | (37) | 45 | (10) | 21,500 | 0 |
| Net income (reported) | (6,832) | 12,147 | 10,451 | 60,068 | 50,375 |
| Net income (normalised) | (6,647) | 12,347 | 10,751 | 60,359 | 50,678 |
| Basic average number of shares, m | 11.68 | 11.86 | 11.99 | 12.09 | 12.09 |
| Basic EPS (CHF c) | (58.5) | 102.4 | 87.2 | 497.0 | 416.8 |
| Adjusted EPS (CHF c) | (56.9) | 104.1 | 89.7 | 499.4 | 419.3 |
| BALANCE SHEET | | | | | |
| Restricted cash | 0 | 22,000 | 0 | 0 | 0 |
| Tangible assets | 2,018 | 4,277 | 3,757 | 3,942 | 4,061 |
| Intangible assets | 632 | 578 | 548 | 457 | 354 |
| Long-term investments | 2,390 | 1,266 | 0 | 0 | 0 |
| Deferred tax assets | 0 | 0 | 0 | 21,500 | 21,500 |
| Other non-current assets | 1,161 | 17,363 | 16,839 | 16,839 | 16,839 |
| Total non-current assets | 6,201 | 45,484 | 21,144 | 42,738 | 42,754 |
| Cash and equivalents | 53,700 | 84,659 | 59,933 | 68,282 | 123,500 |
| Restricted cash | 1,253 | 1,908 | 4,389 | 4,389 | 4,389 |
| Short-term investments | 95,000 | 0 | 0 | 0 | 0 |
| Inventories | 22,783 | 24,244 | 26,410 | 39,467 | 34,120 |
| Trade and other receivables | 24,947 | 33,152 | 27,891 | 35,925 | 38,759 |
| Other current assets | 43,383 | 31,401 | 33,522 | 33,522 | 33,522 |
| Total current assets | 241,066 | 175,364 | 152,145 | 181,586 | 234,290 |
| Convertible senior unsecured bonds (long-term) | 94,544 | 95,000 | 95,455 | 95,455 | 95,455 |
| Senior secured loan | 0 | 36,360 | 0 | 0 | 0 |
| Deferred revenue | 11,926 | 10,693 | 9,460 | 8,227 | 6,994 |
| Non-current operating lease liabilities | 10 | 16,323 | 15,636 | 15,636 | 15,636 |
| Other non-current liabilities | 24,986 | 8,337 | 15,149 | 15,149 | 15,149 |
| Total non-current liabilities | 131,466 | 166,713 | 135,700 | 134,467 | 133,234 |
| Convertible senior unsecured bonds (short-term) | 123,505 | 0 | 0 | 0 | 0 |
| Senior secured loan | 0 | 37,467 | 15,453 | 0 | 0 |
| Accounts payable | 10,617 | 191 | 5,847 | 8,738 | 7,554 |
| Deferred revenue | 1,233 | 1,233 | 1,233 | 1,233 | 1,233 |
| Current operating lease liabilities | 896 | 1,988 | 2,062 | 2,062 | 2,062 |
| Other current liabilities | 38,157 | 33,971 | 22,997 | 22,997 | 22,997 |
| Total current liabilities | 174,408 | 74,850 | 47,592 | 35,030 | 33,846 |
| Net assets | (58,607) | (20,715) | (10,003) | 54,827 | 109,964 |
| CASH FLOW STATEMENT | | | | | |
| Reported net income | (6,831) | 12,147 | 10,451 | 60,068 | 50,375 |
| Depreciation and amortisation | 754 | 1,097 | 1,577 | 1,206 | 1,284 |
| Share based payments | 4,322 | 3,598 | 4,762 | 4,762 | 4,762 |
| Deferred tax | 0 | 0 | 0 | (21,500) | 0 |
| Other adjustments | 1,522 | 497 | 1,443 | 0 | 0 |
| Movements in working capital | (31,787) | (10,282) | (3,988) | (19,434) | 97 |
| Cash from operations (CFO) | (32,020) | 7,057 | 14,245 | 25,102 | 56,518 |
| Capex | (581) | (3,138) | (813) | (1,100) | (1,100) |
| Short-term investments | 6,023 | 94,951 | 0 | 0 | 0 |
| Long-term investments | 0 | 0 | 0 | 0 | 0 |
| Other investing activities | (1,867) | (165) | (221) | (200) | (200) |
| Cash used in investing activities (CFIA) | 3,575 | 91,648 | (1,034) | (1,300) | (1,300) |
| Net proceeds from issue of shares | 42,240 | 250 | (381) | 0 | 0 |
| Movements in debt | (23,212) | (49,672) | (59,314) | (15,453) | 0 |
| Other financing activities | (2,388) | 4,176 | 2,390 | 0 | 0 |
| Cash from financing activities (CFF) | 16,640 | (45,246) | (57,305) | (15,453) | 0 |
| Cash and equivalents at beginning of period | 66,256 | 54,952 | 108,566 | 64,322 | 72,671 |
| Increase/(decrease) in cash and equivalents | (11,805) | 53,459 | (44,094) | 8,349 | 55,218 |
| Effect of FX on cash and equivalents | 501 | 155 | (151) | 0 | 0 |
| Cash and equivalents at end of period | 54,952 | 108,566 | 64,321 | 72,671 | 127,889 |
| Net (debt)/cash | (68,096) | (60,260) | (46,586) | (22,784) | 32,434 |

Source: Company reports, Edison Investment Research

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