

Deinove

Company outlook

Diversified biotech championing antibiotics

Deinove is a biotech company that develops innovative compounds from rare bacteria strains, including the little-explored *Deinococcus* genus. Using proprietary strain-selection technology, the company has collected an extensive library of c 6,000 extremophile bacteria found in hostile environments. Of the many potential compounds identified by Deinove, the most valuable are novel antimicrobials. The lead Phase II-ready asset, DNV3837, is targeting *Clostridium difficile* infection. Drug development efforts are expected to be partly supported by revenue from products for other applications, such as Phyt-N-Resist, the first-ever scaled-up, bio-sourced phytoene for cosmetics. Our valuation is €65m or €4.2/share.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/16	0.8	(7.7)	(0.73)	0.0	N/A	N/A
12/17	0.2	(9.7)	(0.68)	0.0	N/A	N/A
12/18e	0.7	(10.1)	(0.62)	0.0	N/A	N/A
12/19e	1.1	(13.3)	(0.69)	0.0	N/A	N/A

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

Tackling antibiotic resistance crisis

Deinove's product pipeline can be broadly divided into antibiotics and bioactives. The development of new antibiotics has become an especially acute issue in an era of increasing bacterial resistance where even simple infections can be life-threatening. Deinove's R&D pipeline was substantially transformed in early 2018 with the announcement of the all-share acquisition of Austrian drug developer Biovertis (backed by TVM) and its subsidiary Morphochem. This brought a clinical-stage antibiotic, DNV3837 (formerly MCB3837), a small-molecule antibacterial that belongs to the novel quinolonyl-oxazolidinone class. The asset aims to address the lack of effective intravenous treatment for difficult *C. diff* infections and successfully underwent three Phase I trials with the next Phase II trial planned to start in 2019.

Other industrial opportunities to support drug R&D

Deinove has accumulated substantial experience in exploring various industrial applications of its technology and several products could provide income in the near term, supporting the drug development programme. The first product, launched in April 2018, is Phyt-N-Resist (phytoene), a colourless carotenoid that cannot be extracted from in pure form from vegetable sources. Other products include a novel cosmetic ingredient Hebelys, marketed with Greentech since April 2018, a second carotenoid planned to launch in 2019; an undisclosed product under evaluation in partnership with Oléos; and animal feed collaboration with Avril.

Valuation: €65m or €4.2/share

With the acquisition of Morphochem, Deinove has significantly moved towards a drug developer business model with a clear focus on antibiotics. We have made a detailed revision of our valuation model and our updated rNPV stands at €65m or €4.2/share, which includes the lead antibiotic asset DNV3837 and the disclosed bioactive ingredients. The initiation of the Phase II trial with DNV3837 is expected this year, which, if successful, will be a major catalyst for the share price.

Pharma & biotech

14 March 2019

Price €1.6

Market cap €25m

Net cash (€m) at end-H118 9.9

Shares in issue 15.6m

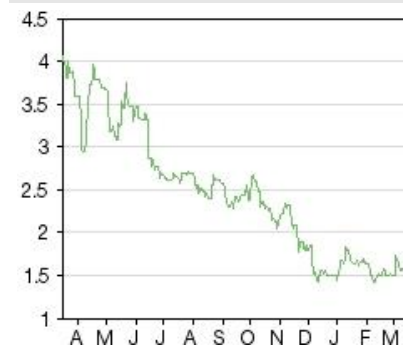
Free float 83%

Code ALDEI

Primary exchange Euronext Growth

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs 6.1 6.4 (60.0)

Rel (local) 1.6 (1.5) (60.0)

52-week high/low €4.1 €1.4

Business description

Deinove is a biotechnology company that discovers, develops and produces high value-added compounds using its state-of-the-art bacterial strain selection, banking, fermentation and screening facilities. The most valuable compounds in the pipeline are novel antimicrobials, with lead asset DNV3837 ready for Phase II trial. Products for other applications, such as cosmetics and nutrition, will support drug development efforts.

Next events

Initiation of Phase II trial with DNV3837 2019

Cosmetics ingredient commercialisation updates H119

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Investment summary

Description: Diversified biotechnology play

Deinove is a biotech company that discovers, develops and produces innovative compounds from rare bacteria strains. It seeks competitive advantage by combining extensive know-how and state-of-the-art bacterial strain selection, banking, fermentation and screening facilities, which allow developing novel compounds for various applications. Deinove possess a collection of more than 6,000 strains, including the little-explored *Deinococcus* genus (40% *Deinococcus*, 60% other rare bacteria). One of the major areas that Deinove is targeting is healthcare, through the development of new antibiotics, which in an era of increasing bacterial resistance is a growing unmet need. Bioactives (primarily cosmetics) is another direction, which also represents the nearest opportunity for income streams that could come in a form of direct sales or payments from partners. Deinove has c 60 employees and was listed on the Euronext Growth market in April 2010.

Valuation: €65m or €4.2/share

We value Deinove at €65m or €4.2/share, using a 12.5% discount rate. From the antibiotics pipeline, we include only the lead asset DNV3837 in our valuation at €2.3/share, but will revisit other compounds as they progress through the preclinical stage. Other products in our valuation are the marketed cosmetics ingredients, Phyt-N-Resist and Hebelys and the disclosed ingredients in development (Oléos, second carotenoid and nutrition). DNV3837 is risk-adjusted with a standard 28% success probability.

Financials: Income from commercial products to support R&D

In its H118 financial results, Deinove reported operating revenue of €715k (vs €140k a year ago), of which €678k were grant payments (related to the Antibiotics against Resistant Infectious aGents [AGIR] programme). Total operating costs amounted to €5.1m and, as previously, the main cost item was salaries and wages at €1.7m vs €1.3m in H117. Cash burn remained fairly stable and largely in line with our expectations. Our revenue forecasts for FY18 and FY19 are €728k and €1.12m, respectively, which mainly reflect grant payments and initial sales of cosmetics products in 2019. Existing cash (€9.9m at end-H118), incoming grant stream and extended equity lines are sufficient to fund existing operations until 2020 and to initiate the Phase II trial with DNV3837. We expect that the next fund-raise will focus significantly on supporting the DNV3837 asset to reach the Phase II readout, which represents an opportunity for value inflection.

Sensitivities: Biotech risks apply

Deinove remains at an early stage of its development and the commercialised cosmetics products have not yet delivered meaningful sales, while products in development still carry R&D risk. In addition to forecasting any commercial revenues, the timing of any such revenues also remains difficult to predict. With the acquisition of Biovertis, Deinove has substantially moved towards a biotech business model with a higher risk, higher reward profile. This could, to some extent, be mitigated if the products commercialised in other sectors (cosmetics and nutrition) are successful and bring in cash flows, which could partially offset investments in antibiotics development. Drug development is capital-intensive and the company will either need to raise additional funds for clinical development or find a partner. The acquisition of Biovertis has been structured as an all-share transaction, but the new shares will be issued as certain milestones are met, which could result in a maximum dilution by issuing 8.0m new shares.

Rare bacteria strains for multiple applications

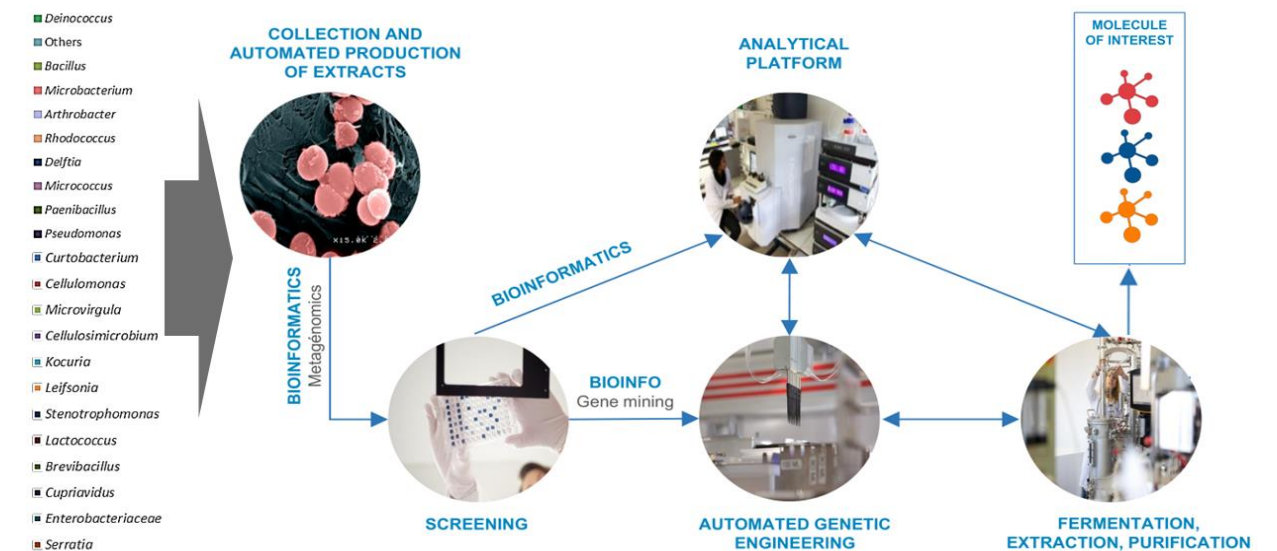
Deinove has state-of-the-art rare bacteria strain banking, fermentation and screening facilities, with patented strain-selection technology based on their UV resistance. This allowed the company to collect strains with potential industrial applications. One of the differentiating elements of Deinove's strain library is the *Deinococcus* bacterial genus, which was discovered in 1956 and has [exceptional](#) properties to withstand the lethal effects of DNA-damaging agents, such as ionising radiation, UV light and desiccation, but has never been explored for industrial purposes. *Deinococcus* is used in the production process of Deinove's Phyt-N-Resist (phytoene) cosmetics ingredient product.

The *Deinococcus* genus was the focus of the original research based on which Deinove was founded; the bacteria strain bank was later expanded and the company currently owns c 6,000 strains, which, besides the *Deinococcus* genus (c 2,500 strains), includes other rare strains (3,500). In addition, the company is constantly seeking to expand the library by partnering with other companies that can provide access to their own libraries; for example, agreements were recently signed with bioMérieux and Naicons, opening access to libraries with other c 650 bacterial strains.

The expanding bank of rare bacteria strains and state-of-the-art infrastructure allow Deinove to screen and identify bacteria that naturally produce compounds of interest, which can then be extracted for further exploration. Deinove, using its know-how gained since establishment in 2006, can optimise the bacterial production via genetic engineering and fermentation processes. This results in an overproduction of a specific compound of interest. Deinove can scale this process to levels required for further R&D of the compounds. Once the product is commercialised, Deinove seeks partners to scale the production to necessary industrial levels. The company's infrastructure includes:

- a strain conservation system – ensures sustainability of the strain bank;
- a screening platform for various applications, especially antibiotics and cosmetics;
- a bioinformatics platform – allows identification of bacteria and genes involved in the production of the compound of interest;
- automated genetic engineering platform – allows the optimisation of strains to produce desired compounds with various modifications; and
- a fermentation engineering and extraction and purification platform – allow pre-industrial production and optimisation of production performance.

Exhibit 1: Deinove's technology platform



Source: Deinove

Significant and growing unmet need for new antibiotics

Historically, Deinove was focused on industrial biotechnology applications using its proprietary fermentation-based natural production methods, with the aim of reducing the environmental impact of traditional mainly oil-derived chemical synthesis models. One of the key programmes in earlier years was biofuels; however, with oil prices remaining at a low level, Deinove suspended the programme. The company identified the *Deinococci* ability to produce antibiotics and antifungals early on and in 2009 launched the exploratory AGIR programme (the Antibiotics against Resistant Infectious aGents). In 2012, this matured into a private company, Deinobiotics, backed by an external investor. Deinobiotics identified several dozen bacterial strains that produce antibacterial activity and, in January 2017, all shares were acquired by Deinove. This AGIR programme was selected by the Investments for the Future Programme (run by Bpifrance) to receive financial support of €14.6m over five years for a total budget of €25m.

While unmet needs in many other therapeutics areas are being addressed with advances in drug development industry, paradoxically the need for new anti-infectives is growing. This is a result of several underlying trends including **slowdown of the development of novel antibiotics**, **increased focus on on-label prescription** and **growing antibiotic resistance**.

- The rate of **development of new antibiotics has slowed** considerably since the 1980s. The pharmaceutical model of developing new antimicrobials for the retail market, so that millions of prescriptions could be written by thousands of primary care physicians who were visited by thousands of sales reps every day, fell out of favour after those original blockbuster drugs went off-patent. This resulted in a focus on hospital and specialist drugs and later on caused an industry-wide feeling that with so many antimicrobial agents available, there was little commercial need to develop new ones.
- When new antimicrobial agents were approved before the late 1980s, they were generally indication independent and the physicians decided which antibiotic was most appropriate for the infection. Later on, **approvals became indication specific** and, today, the off-label prescribing of antimicrobial agents outside their approved indications presents barriers including reimbursement challenges, litigation risks and unwanted deviation from guidelines. Such a situation continues to favour new antibiotic development for specific indications.

- Finally, the most concerning macro trend is **antimicrobial resistance**, the ability of a microbe to evolve resistance to an anti-infective medication. Due to the increased resistance of pathogens, in part due to the misuse and over-prescription of existing antibiotics, there is now a significant need for antibiotic drugs with novel or differentiated mechanism of action, as even previously easy-to-treat infections are causing life-threatening conditions. The US Centers for Disease Control and Prevention (CDC) estimates at that least 23,000 deaths and more than two million illnesses annually in the US alone are as a result of antimicrobial resistance.

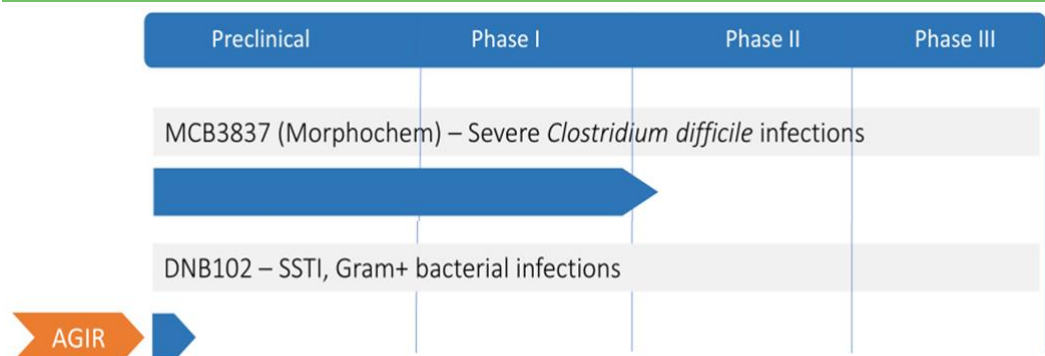
To combat this ‘antibiotic crisis’, a number of public initiatives have been proposed to encourage antimicrobial drug development:

- FDA and EMA fast-track designations that enable faster submissions and regulatory reviews.
- FDA Qualified Infectious Disease Product Designation (QIDP) granted under the Generating Antibiotic Incentives Now (GAIN) legislation, with priority review on first application and five years of additional market exclusivity.
- The US 21st Century Cures Act established the limited population pathway for antibacterial and antifungal drugs (LPAD) reducing the hurdle of evidence needed to approved novel antibiotics.
- The REVAMP Act 2018 is US bipartisan legislation to incentivise antimicrobial development including an extra year of market exclusivity.
- New technology add-on payments (NTAP) have been granted by CMS to encourage the use of antibiotics in new hospital indications, providing additional funding for products that would not otherwise be covered by Medicare on their introduction.

Deinobiotics: The backbone of the drug development programme

The macro trends described above provide opportunities for antibiotic developers. Deinobiotics, which is now a wholly-owned subsidiary of Deinove, aims to develop a portfolio of drug candidates (Exhibit 2). The original work conducted within Deinobiotics resulted in the identification of a new class of antibiotics with demonstrated *in vitro* activity and two patent applications were filed. The next step in this project (DNB102) is the optimisation of the novel antibiotic structure. In order to grow the R&D portfolio faster, Deinove acquired Biovertis, which via its subsidiary Morphochem brought the most advanced antibiotic in the pipeline, DNV3837 (formerly MCB3837), ready for Phase II trial.

Exhibit 2: Deinobiotics’ R&D pipeline



Source: Deinove. Note: DNV3837 is the new MCB3837 branding.

While offering substantial upside to investments, as with any innovative drug, the development timelines can be lengthy and uncertain (Exhibit 3). Historical approval rates for systemic antibiotics

are around **19%** from start of Phase I studies to approval. From Phase II to approval the historical success probability for anti-infectives stands around 28%, which we use in our model.

Exhibit 3: Drug development process

Step/phase	Description
Discovery and preclinical development	Discovery of new drugs can occur in a number of ways. Once molecule of interest is obtained, <i>in vitro</i> and <i>in vivo</i> testing provide detailed information on dosing and toxicity levels to be aware of in clinical development.
Clinical development	Trials in people to establish the safety of the drug and answer specific research questions take place in a number of phases.
- Phase I	20–100 volunteers or patients. Goal is to establish safety and dosage. Can last several months with c 70% of drugs proceeding to the next stage.
- Phase II	Tests on a larger group of people with the disease (several hundred) for efficacy and side effects. Can take two or more years. Typically 33% of drugs pass on to the next stage.
- Phase III	Tests for efficacy and adverse effects on a larger group of people (several hundred to thousands). This phase usually lasts between two and four years. 5–30% of drugs pass to the next phase.
NDA	New drug application (NDA) is submitted to regulatory authorities as a part of the approval process, takes several months.
Market	Commercial phase. Sometimes involves a Phase IV clinical trial if there are any remaining safety concerns.

Source: [di Masi et al.](#)

Biovertis/Morphochem acquisition adds mid-stage project

The proposed acquisition was for an initial consideration of 500,001 Deinove shares with warrants attached (priced at €1.8/share, the closing share price on 17 January 2018 – the last trading day preceding the signature of a letter of intent between the parties). The new shares represented c 4% of Deinove’s capital following the transaction, which was approved at the AGM in May 2018.

The warrants attached to the issue of the original 500k shares could add 8m new shares, but will only become exercisable if the drug candidate reaches identified milestones (Exhibit 4). We note that these milestones are also typical catalysts for the share price in drug development. TVM is a group of independent investment advisories and fund managers for VC funds investing in the biotech, pharma and medtech sectors. TVM currently manages c €900m of investments for more than 50 investors. The deal is dependent on Deinove having sufficient financial resources to ensure a ‘going concern’ status and as such it has announced that it will proceed with attempts to raise funds from a variety of sources, including a potential issue of equity. TVM has already contributed €2m as part of the share issue carried out in June 2018 and has a presence on Deinove’s board of directors.

Exhibit 4: Milestones for DNV3837 relating to exercise of warrants

Number of shares to be issued	Milestone
500,001	Beginning of the project’s next clinical trial (first patient in)
2,300,000	Start of the project’s Phase IIb/III pivotal trial or Phase III
2,300,003	Positive end to Phase IIb/III trial (positive = efficacy primary of clinical endpoints + at least one secondary endpoint + confirmed safety)
1,399,998	FDA acceptance of regulatory filing for the marketing approval in the US (or other countries with equivalent market value)
1,499,998	First marketing approval of the project in the US or markets with an equivalent market value

Source: Deinove

C. diff: Opportunistic, difficult-to-treat infection

Morphochem, based in Munich, developed a clinical stage antibiotic MCB3837 compound (that Deinove renamed to DNV3837) designed to treat difficult infections caused by C. diff. DNV3837 is a small-molecule antibacterial that belongs to the novel quinolonyl-oxazolidinone class.

C. diff is a Gram+, anaerobic, spore-forming bacillus that was first identified in 1978 as the likely bacteria causing antibiotic-associated diarrhoea and so-called pseudomembranous colitis (PMC).¹

¹ Daryl D. DePestel et al. Epidemiology of Clostridium difficile Infection. J Pharm Pract. [2013 Oct; 26\(5\): 464–475.](#)

The manifestations of *C. diff* infection can range from asymptomatic colonization to mild diarrheal illness, but in certain cases it can cause severe gastrointestinal infections and particularly affects those with weak immune systems (eg elderly or those with a damaged gut) and in extreme cases resulting in toxic megacolon, sepsis and death. Historically, *C. diff* infection was considered a complication of antibiotic therapy prescribed for other infections resulting in disbalance of normal gut bacteria and overgrowth of *C. diff* leading to symptoms. Following the identification of the bacteria, the consensus was that the infection can be successfully treated (metronidazole or vancomycin) and was not thought to be a cause for a major public concern. Over the last 10–15 years, however, *C. diff* infection reemerged as a serious infectious disease, occurring more frequently with increased severity and was more refractory to standard therapy.¹ More *C. diff* infections are being diagnosed in what used to be considered low-risk populations, such as antibiotic-naïve patients.

Incidence and target population for DNV3837

The incidence of *C. diff* has increased significantly over the past 20 years in most western countries. The US CDC Emerging Infections Program (EIP) recorded a *C. diff* incidence of 141.8 cases per 100,000 people in 2013. Using various sources, Global Data estimated that c 586k cases were diagnosed in the US and c 141k cases in top five European countries in 2018. Global Data notes that the incidence rates of *C. diff* infection in Europe vary widely and are difficult to estimate due to the lack of standardised national surveillance systems and diverse methods of reporting. In addition, *C. diff* infection severity classifications are not used consistently across markets. The significant difference in recorded cases of *C. diff* infection between the US and Europe can be explained by a strict surveillance system in the US, differences in the diagnostic methods and antibiotic consumption rates in those markets.

According to Global Data, severe or severe and complicated cases account for around half of the total incidence, so 294k in the US and 64k in the top five European countries. This also represents the initial target population for DNV3837. For our model we extrapolated the prevalence in the top five countries to the top 14 countries in Europe and arrive at 79k of *C. diff* infection cases per year. As a result, **we use annual incidence of 294k of severe cases in the US and 79k in Europe in our model.** In its latest update, Deinove indicated the upcoming trial will also recruit moderate *C. diff* infection patients, so there is possibility for the target population to expand further. But until we will have more visibility on specific patient selection criteria, we use the incidence rate of severe cases in our model.

Recurrence of *C. diff* infection occurs in approximately 25% of successfully treated patients ([O. A. Cornely et al](#)). Strikingly, the recurrence rate increases further to 50–65% in patients who have experienced more than two episodes ([DePestel and Aronoff, 2014](#)).

Changing *C. diff* infection treatment paradigm

Asymptomatic carriers of *C. diff* do not receive any treatment due to lack of any benefits of an intervention, while those with symptomatic infections are usually treated with antibiotic, although there are efforts to introduce non-antibiotic options (antibodies, microbiome modulators, faecal microbiota transplantation). Specific treatment of the *C. diff* infection varies according to the severity. According to the [updated guidelines](#), discontinuation of the antibiotic therapy, which caused overgrowth of *C. diff*, should be the first-line measure. In moderate to severe case vancomycin and fidaxomicin (Dificid, Merck & Co/Astellas) are recommended as first-line antibiotics. The revised guidelines no longer recommend metronidazole as first-line therapy due to increasing resistance rates; previously it was the first-line option. Bezlotoxumab (Zinplava, Merck & Co), a monoclonal antibody against *C. diff* toxin B, is used in relapse cases or for individuals with a high risk of recurrence. Faecal microbiota transplantation is recommended for patients with multiple recurrences.

Dificid (fidaxomicin), an orally administered narrow spectrum macrocyclic antibiotic, is a newer branded antibiotic that selectively eradicates *C. diff* and was developed by Optimer Pharmaceuticals to address increasing *C. diff* resistance to classic antibiotics and high recurrence rates. Clinical trials with fidaxomicin showed good results with the drug being non-inferior to vancomycin and demonstrated lower recurrence rate; however, it was priced as a branded drug, therefore the initial commercial launch was challenging after the approval in 2011. Optimer was acquired by Cubist Pharmaceuticals and later by Merck & Co in 2015 and, according to EvaluatePharma, Dificid brought \$133m in sales in 2018. The [newest guidelines](#) from the Infectious Disease Society of America (IDSA) released in February 2018 now recommend Dificid as first-line choice next to vancomycin.

Exhibit 5: C. diff infection treatment in market and late-stage R&D

Class	Drug	Company	Stage	2018 revenues	Annual cost of therapy
Antibiotics	Vancomycin hydrochloride (oral)	Various	Marketed (WW)	Generic	\$1,340 (US) \$300–570 (EU5)
	Metronidazole (off-label use)	Various	Marketed (WW)	Generic	\$45 (US) \$1–12 (EU5)
	Dificid (fidaxomicin) (oral)	Astellas Pharma, Merck & Co	Marketed (WW)	\$133m	\$3,700 (US) \$1,700–1,900 (EU5)
	Ridinilazole (oral)	Summit Therapeutics	Phase III	-	-
Antibodies	Zinplava (bezlotoxumab)	Merck & Co	Marketed	\$102m	\$3,100 (US) \$1,200–1,500 (EU5)
Microbiome modulators	RBX2660	Ferring	Phase III	-	-
	SER-109	Seres	Phase III	-	-

Source: EvaluatePharma, Global Data, Clinicaltrials.gov, Edison Investment Research. Sales data from EvaluatePharma. Annual cost data from Global Data.

The antibiotics against *C. diff* are mainly given orally (metronidazole could also be given intravenously as a last resort, but that would be an off-label use). This means that effective antibiotic treatment of severe *C. diff* is still lacking as oral treatments struggle to reach the intestines because of the patient's pathological condition, while intravenous antibiotics do not penetrate the gastrointestinal barrier and therefore do not reach the site of infection. DNV3837 is administered intravenously and designed to cross the gastrointestinal barrier and target the gut, the site of the infection, more effectively than orally administered antibiotics. There are two intravenous antibiotics administered against severe *C. diff*: metronidazole and tigecycline. As discussed, metronidazole is mostly used orally and, due to increasing resistance, it is no longer recommended as front-line therapy, while no controlled trials with tigecycline have been conducted in *C. diff* infections ([IDSA guidelines](#)). The lack of a regulatory approved intravenous treatment option and a growing incidence of *C. diff* present a significant opportunity for DNV3837, in our view.

Exhibit 6: Antibacterial treatments for C. diff and activity ranges

Antibacterial	Routes	Phase	MIC range mg/L
MCB3681 (DNV3837*)	IV	Phase I	0.008–0.5
Metronidazole	IV/oral	Off-label	0.125–2
Vancomycin	Oral	Marketed	0.125–1
Fidaxomicin	Oral	Marketed	0.008–0.125
Tigecycline**	IV	Off-label	0.032–0.1
Ridinilazole	Oral	Phase II	0.125–0.5
CRS3123	Oral	Phase I	0.5–1

Source: Morphochem, poster presentation ECCMID, April 2015. DNV3837 is the prodrug of the DNV3681 molecule; ** Tigecycline is wide spectrum, not specific to *C. diff*.

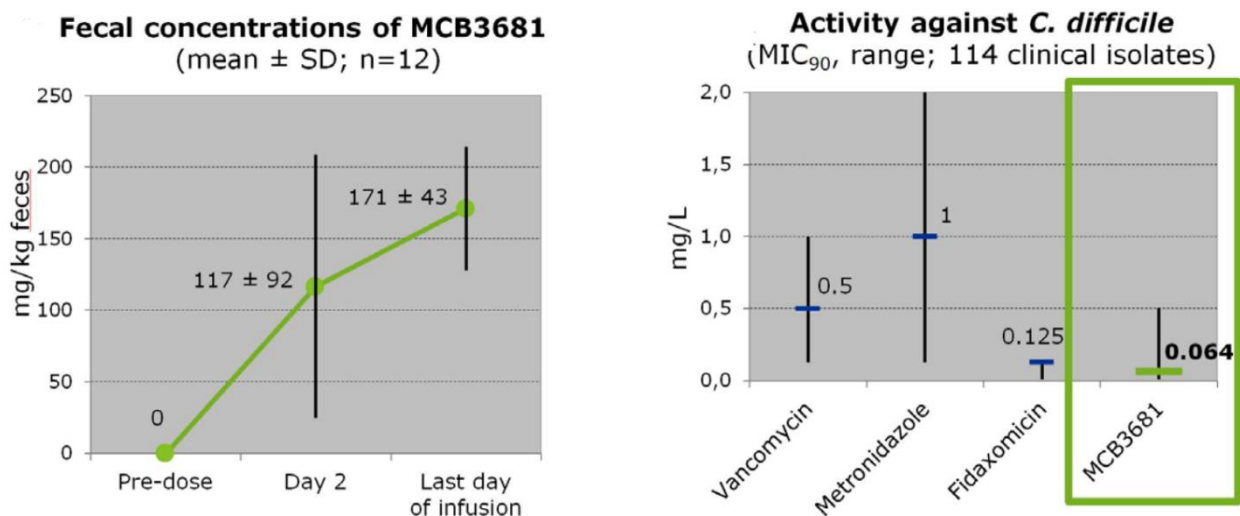
Late-stage drugs in development include Summit Therapeutics' Ridinilazole, another antibiotic, and two microbiome modulators: RBX2660 (Ferring) and SER-109 (Seres). A notable development in the space could be the introduction of vaccines; for example, Pfizer's vaccine PF-06425090, which is in late-stage development. However, none are approved yet and one of the key questions is what target population would be suitable for prophylactic vaccination against *C. diff*, ie blanket vaccination of, for example, all in-hospital patients receiving antibiotic therapy could be effective,

but risks of such a large vaccination campaign are still unknown and the financial burden would be immense.

DNV3837 Phase I data

Three Phase I trials with c 90 healthy volunteers have shown a good safety/tolerability profile and a high concentration of the antibiotic in stools, which is a strong marker of its presence in the intestine. It has demonstrated an ability to eliminate *C. diff* bacteria without destroying other microorganisms of the gastrointestinal flora, ie aerobic and anaerobic Gram-negative species in humans are not affected. The drug was granted the qualified infectious disease products (QIPD) designation as well as fast-track status from the US FDA. The QDIP designation provides an additional five years of marketing exclusivity. The next stage of development will be a Phase II clinical trial with a small number of patients.

Exhibit 7: DNV3837 (formerly MCB3681) Phase I data



Source: Morphochem, poster presentation ECCMID, April 2015

AGIR project: DNV series compounds and external partnerships

In 2017, Deinove's AGIR project was selected by the Investments for the Future Programme (established by Bpifrance) to receive financing support of €14.6m over five years. Deinove will receive €10.4m, while the Charles Viollette Institute, a partner of the project, will receive €4.2m. The total budget of the project is €25m. So far, the Deinobiotics project has identified several bacterial strains of interest from its own library and two patent applications have been filed (published in January 2017) for a new antibiotic structure, DNB101. This is a novel, previously unstudied, molecule with demonstrated *in vitro* activity against Gram-positive bacteria and is currently undergoing optimisation (DNB102).

Exhibit 8: DNV101 antimicrobial activity

Strains	MIC ₉₀ (µg/MI)	Strains	MIC ₉₀ (µg/MI)
<i>S. aureus</i> [MSSA & MRSA]	2	<i>C. difficile</i>	0.125
<i>S. epidermidis</i> [MSSA & MRSA]	0.5	<i>P. acnes</i>	0.03
<i>E. faecium</i> [Vancomycin S&R]	0.5	<i>E. coli</i>	>4
<i>E. faecalis</i>	>4	<i>P. aeruginosa</i>	>4
<i>S. pneumoniae</i>	0.125	<i>C. albicans</i>	>4

Source: Deinove

As part of the AGIR project, Deinove also has established partnerships in order to access outside bacterial strain libraries. In March 2018, Deinove revealed that it had entered into collaboration with the Italian biopharmaceutical company, **Naicons**. Naicons (founded in 2006) is also focused on

research designed to discover new antibiotics (from natural products) and has a collection of 45,000 microbial strains. Naicons' strategy is to advance novel compounds to a point of significant value creation and then license out. The company seeks to finance itself with research grants and collaborations with partners and, since its inception, it has out-licensed two products and secured several million euros in research grants. Under the terms of the agreement, Deinove will have access to 400 selected strains from Naicons' portfolio and will use its robotic technology platform to screen these strains. If Deinove discovers a bacteria strain of interest, under the terms of the agreement, it can acquire it either via a commercial licence or in full ownership, in order to initiate the drug development.

Seeking to further exploit the beneficial conditions of the AGIR project, Deinove entered into another similar partnership with **bioMérieux** in June 2018, which will also provide access to a third-party bacterial strain library. BioMérieux specialises in the infectious disease diagnosis and has one of the largest bacterial strain banks in the world. Deinove will initially have access to over 250 strains from 130 different species.

The most recent collaboration agreement with **Calibr** announced in October 2018 is slightly different. Calibr is a drug discovery division of the non-profit Scripps Research corporation in California (one of the largest non-profit biomedical research organizations in the world). As part of this collaboration, Deinove will provide bacterial extracts that will be evaluated by Calibr in infections not targeted by Deinove, such as malaria and tuberculosis.

As can be seen from above Deinove is focused on building its antibiotic pipeline using various sources, but at the same time employs strict quality criteria to screen for new assets before committing financially. A recent example of such careful evaluation was a licence option agreement with the UK-based RedX Pharma, announced in March 2018. The agreement involved RedX's first-in-class, anti-infective programme, Novel Bacterial Topoisomerase Inhibitor, targeting Gram-negative infections such as *Acinetobacter baumannii* and *Pseudomonas aeruginosa*, which tend to cause treatment-resistant, life-threatening infections, such as hospital-based (nosocomial) pneumonia. The project therefore met the criteria of novelty and unmet need, but after the evaluation period Deinove decided not to in-license the drug indicating that the additional work needed to optimize the compound could not be justified at that time. We expect the company to continue actively assessing other potential opportunities in the future as well.

Cosmetics ingredients of natural origin

The aim of Deinove's Bioactives programme is to provide a range of naturally produced, alternative, quality, sustainable and cost-effective bioactives for various industries. The two most-explored directions so far are the cosmetics and animal nutrition sectors. Deinove believes there will be significant growth in the market for cosmetics due to a growing and ageing population, and increasing global affluence. Research and Markets sees an overall cosmetics market of \$131bn (2016) growing at a CAGR of c 4.7-5.3% until 2023. According to Deinove, the target market for carotenoids is c \$1.8bn with a selling price of between €300/kg and €3,000/kg, depending on the molecule. The production costs are estimated to be in the range of €200–600/kg.

The *Deinococcus* genus, discovered in 1956, has unexplored genetic and metabolic properties, potentially useful for industrial purposes. *Deinococci* bacteria are robust and able to withstand harsh fermentation conditions, radiation and solvents that other bacteria might find toxic. The bacteria also have the potential to resist temperatures of 30–60°C and a pH range of 3–10. The robustness of the *Deinococcus* bacterium and its ability to reassemble the genome when damaged make it an attractive option for industrial applications. These are Gram-positive bacteria with a second membrane, therefore structurally close to Gram-negative bacteria. The two main characteristics are the presence of a carotenoid pigment that gives a pink colour and a high

resistance to gamma and UV radiation. Some 400 *Deinococcus* strains naturally produce carotenoids, including the best-known Deinoxanthin. According to Deinove, using its proprietary optimisation technology, the company has managed to produce five other types of carotenoids that have commercial potential due to being in one way or another superior compared to currently used carotenoids.

Phyt-N-Resist – first commercial phytoene product

Most existing carotenoids are made from petrochemical sources and are known for their colouring, antioxidant and photochemical properties. As such, carotenoids are used in food supplementation and cosmetics as colouring agents. Although carotenoids can be extracted from plants, the process is costly and the yields remain low. Deinove is aiming to produce carotenoids using its technology and believes it can offer advantages in terms of quality and stability of supply, conservation of resources and costs.

Phyt-N-Resist is the first internally developed product and consists of concentrated phytoene, a colourless carotenoid that cannot be extracted from pure vegetable sources. Phytoene was produced from the fermentation of *Deinococcus* bacteria in refined jojoba oil. In evaluation studies, Deinove has shown ([slide 39](#) in the corporate presentation) that it reduces the harmful effects of oxidation, promotes skin regeneration and wrinkle reduction. Previously, it was impossible to extract pure phytoene with vegetable extraction processes, allowing only the extraction of a less concentrated mixture of various carotenoids.

Deinove launched the product in April 2018 and established distribution agreements covering the main geographies. Univar is taking care of the [commercial promotion and distribution](#) of Phyt-N-Resist in the EMEA zone from 1 October 2018, while Solvay Novincare is marketing it in North America and Asia (no financial details disclosed). Although developed internally using its own technology platform, Deinove plans to market it in the form of an ingredient to manufacturers, but does not plan to develop its own industrial-scale manufacturing facilities. Instead, these processes were outsourced (fermentation on an industrial-scale to SAS Pivert, and extraction to Veg'Extra), while Deinove is focusing its own capacity on other R&D activities. According to the most recent update, a number of business partner contacts were established, including with finished cosmetics products brands that are now assessing the ingredient.

In November 2018, Deinove announced that it is developing a second carotenoid for cosmetic applications. If all goes to plan the company could start market the new ingredient in 2019, but further details remain confidential.

Hebelys

Deinove has also announced the launch of a second cosmetics product, Hebelys, the fruit of its collaboration with Greentech, with which the company has been working since March 2017. Greentech, a French company founded in 1992, is focused on plant biotechnology developing and producing active ingredients from plant, marine and microbial worlds for application in the cosmetic, nutraceutical and pharmaceutical fields. Greentech's laboratory has a database of 30,000 plants and 300,000 biomolecules, and today markets around 100 active ingredients to cosmetic manufacturers in more than 30 countries. Hebelys is an anti-ageing active ingredient obtained through fermentation of the *Sphingomonas* bacteria and, according to Deinove, has demonstrated an ability to preserve youthful skin (in particular providing protection against oxidation), an ability to stimulate collagen and elastin, and fibrillin synthesis.

Oléos

At the end of January 2018, Deinove entered into a partnership with Hallstar's Oléos group to develop natural cosmetic active ingredients. The Oléos Group was acquired by US speciality

chemistry company, Hallstar, based in Chicago. Oléos already possesses a range of natural active ingredients (over 20) that it markets to cosmetic companies and is seeking to expand its range further via its partnership with Deinove. Oléos is also located in Montpellier and has developed a proprietary oleo-eco-extraction technology designed to produce natural and sustainable compounds for cosmetic applications, including anti-ageing qualities, dark spot diminishment and skin whitening. Deinove works to optimise the production and fermentation of the selected strain, while Oléos is working on extraction and formulation of the innovative ingredients. Details on the class of the compounds were not disclosed, but the companies aim to obtain an active ingredient stable in oil with clinically demonstrable cosmetic efficacy. In May 2018, both companies extended the partnership to develop a second oleo-active ingredient and aim to launch one or two active ingredients in the next two years.

Nutrition

Like the antibiotic development, the nutrition business also benefits from significant macroeconomic drivers. A burgeoning global population will require enhanced arable yield and improved livestock production to fulfil nutritional requirements. Deinove's nutrition business seeks to help address these global challenges via its commercial partnership Avril and through its own carotenoid programme.

Deinove signed an agreement with **Avril** (formerly Sofiprotéol) in 2014 to develop new animal nutrition products. Avril, founded in 1983, is a private French company that focuses on the oil and protein sector, with operations extending into renewable chemistry, human and animal nutrition, and renewable energy. The project, named COLOR2B, is divided into three stages; the first screening stage identified 20 strains of interest and was completed in 2015. The second stage, including fermentation, optimisation extraction characterisation and preliminary animal testing, was successfully completed with the potential (effectiveness and bioavailability) of Deinove's strains validated by Avril. The compounds produced were well assimilated and have produced the desired beneficial effects when added into the feed of farm animals. The final stage of the project is ongoing and the most promising strain has been selected; Avril is testing the feed ingredient in various animal species.

Intellectual property

Deinove has developed a portfolio of intellectual property to protect its bacterial strains and various steps of the technology platform. The IP portfolio currently includes 22 patent families representing over 160 patent applications submitted internationally and covering strain selection, culture and engineering techniques, and their applications in the target markets. Furthermore, following the acquisition of Morphochem, Deinove has enhanced its intellectual property portfolio with six categories of patents representing over 100 international patent applications covering the now lead asset, DNV3837.

Sensitivities

Deinove remains at an early stage of its development and the commercialised products still have unproven market potential, while products in the development still carry R&D risk. In addition to forecasting the magnitude of any commercial revenues, the timing of any such revenues also remains difficult to predict. Variations to the timing of receipt of revenues would affect our DCF valuation and could alter the financing requirements of the business. With the acquisition of

Biovertis, Deinove has substantially moved towards a biotech business model with a higher risk, higher reward profile. This could, to some extent, be mitigated if the products commercialised in other sectors (cosmetics and nutrition) are successful and bring in cash flow, which could partially offset investments in antibiotics development. Drug development is capital-intensive and the company will either need to raise additional funds for clinical development or find a partner. The acquisition of Biovertis has been structured as an all-share transaction, but the new shares will be issued as certain milestones are met. Therefore, new investors should pay attention to the specific triggering milestones; however, if met, these events are likely to create substantial value. The total number of new shares that could be issued if all milestones are met is 8.0m.

Valuation

With the acquisition of Morphochem, Deinove has significantly moved towards a drug developer business model with a clear focus on antibiotics. We have made a detailed revision of our valuation model to reflect such rebalancing and our updated risk-adjusted NPV stands at €65m or €4.2/share. We note that as of end-H118 there were unexercised share warrants and options amounting to c 10.9m, however, absolute majority (8.0m) of those were related to the acquisition of Biovertis/Morphochem. The warrants associated with the later become exercisable only after certain milestones are met, which are related to clinical development. Each of these milestones is related to positive R&D developments, which typically provides catalysts for the share price.

From the antibiotics pipeline, we include only the lead asset DNV3837 in our valuation at €2.3/share. Other products in our valuation are the two marketed cosmetics ingredients, Phyt-N-Resist and Hebelys and other disclosed products: cosmetics ingredients being developed with Oléos, a second carotenoid developed internally and to be launched in 2019 and a nutrition ingredient. Notably, we risk-adjust DNV3837 with historical 28% success probability to reach the market. Cash flows from marketed products are included at 100%. We include estimated net debt of €3.0m at end-2018 and use a 12.5% discount rate. The main assumptions underpinning our rNPV model are (more details in Exhibit 10):

- **Antibiotics.** We assume a severe C. diff infection patient population in the US and top 14 European countries (c 294k cases per year in the US and c 79k in top 14 European countries). We assume peak market penetration of 15%. A price of \$2,500 and \$1,500 per treatment in the US and Europe, respectively, which represent discount to the average prices of Difidid (see Exhibit 5). As discussed, premium pricing of Difidid was one of the key hurdles for more widespread use of it even though it is now included in the guidelines as a front line option. We assume that Deinove will finance Phase II (€12.5m) and Phase III (€20m) costs and will secure a licensing deal afterwards with deal terms: €62m in upfront payment and €163m in milestone payments (we used the [Astellas](#) and [Optimer](#) deal as a benchmark). We assume a 17-20% royalty rate. We also assume out-licensing after Phase III, but this could happen also after Phase II depending on the company's strategic decision and available financing.
- **Cosmetics & Nutrition.** Deinove currently markets internally-developed **Phyt-N-Resist** via distributors and **Hebelys**, developed and commercialized in partnership with Greentech. **Second internally-developed carotenoid** is planned for launch in 2019. Deinove has also reported that it is working with **Oléos** on at least two ingredients. Collaboration with Avril may bring a **nutrition ingredient** on the market. So far, the company has not yet booked sales from these products, so little visibility exists as to the market potential that could be reached. Our assumptions that underpin cosmetics and nutrition ingredients' potential (5 projects in the model in total) are listed in Exhibit 10.

Exhibit 9: DCF valuation of Deinove (operations including ingredients)

(€m)	2019e	2020e	2021e	2022e	2023e	2024e	2025e	2026e	2027e	2028e	2029e	2030e
EBIT (risk-adjusted)	(10.8)	(10.5)	(6.1)	(0.0)	3.2	6.1	7.9	8.6	9.8	10.5	11.3	12.0
Tax	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
D&A	1.9	1.6	1.1	1.1	1.1	1.1	1.1	1.1	0.6	0.6	0.6	0.6
Change in WC	2.8	(1.6)	(0.1)	(1.5)	(1.2)	(2.2)	0.0	(0.1)	0.5	0.5	1.1	0.5
Capex	(0.8)	(0.6)	(0.6)	(0.6)	(0.6)	(0.6)	(0.6)	(0.6)	(0.6)	(0.6)	(0.6)	(0.6)
Operating FCF	(6.9)	(11.0)	(5.8)	(1.1)	2.5	4.4	8.4	9.0	10.3	11.0	12.3	12.6
												rNPV (€m)
Free cash flows FY19–30e												4.6
Terminal value (1.5% growth rate assumed)												28.2
Total value												32.8
Valuation/share (€)												2.1

Sum-of-the-parts Deinove valuation (operations including ingredients and antibiotic)

Product	Launch	Peak sales (€m)	Unrisked NPV (€m)	Unrisked NPV/share (€)	Probability (%)	rNPV (€m)	Value per share (€)
Antibiotics (C. diff)	2025	209	125.9	8.1	27.5%	35.9	2.3
Bioactives (DCF)						32.8	2.1
Estimated net debt at end-2018						(3.7)	(0.2)
Valuation						65.0	4.2

Source: Edison Investment Research. Discount rate 12.5%. DCF taxes are offset by tax loss carryforward (€54.4m in 2017)

Exhibit 10: Assumptions for R&D projects and ingredients business

Product / stage	Comments
DNV3837 - Phase II ready - C. diff infection	<p><u>Market potential:</u> €210m peak sales estimate. Severe C. diff infections of c 294k cases per year in the US and c 79k in top 14 European countries. 15% market penetration with peak sales achieved over a period of 6 years.</p> <p><u>R&D costs and timelines:</u> €12.5m for Phase II split over 2019-2021; €20.0m for Phase III split over 2022-2023. Launch in 2025.</p> <p><u>Licensing terms:</u> Out-licensing after Phase III with an upfront payment of €62m, a total of €163m in potential milestone payments and mid to high double-digit royalties. Deal terms are based on comparable Astellas and Optimer agreement for Fidaxomicin. This included only territories in Japan, Europe and certain other smaller markets, but not the US. Therefore we believe these terms could be conservative.</p>
Cosmetics & Nutrition	<p><u>Volumes:</u></p> <ul style="list-style-type: none"> - 25mt Phyt-N-Resist and 2nd carotenoid each at peak (reached 6 years after launch). - 20mt For Hebelys, Oléos and nutrition ingredients each at peak. <p><u>Price:</u></p> <ul style="list-style-type: none"> - €1,000/kg for Phyt-N-Resist and 2nd carotenoid, nutrition; - €500/kg for Hebelys, Oléos and nutrition. <p><u>Timelines:</u> Phyt-N-Resist and Hebelys already launched, first sales expected in 2019. Oléos, 2nd carotenoid and nutrition ingredient to be launched in 2019/2020.</p> <p><u>Sales and marketing:</u></p> <ul style="list-style-type: none"> - Phyt-N-Resist and 2nd carotenoid developed internally, manufactured (COGS €400/kg) and marketed via distributors (50% transfer pricing, ie Deinove receives 50% of the end user pricing shown above). - Oléos, Hebelys and nutrition ingredients co-developed and marketed by respective partners. Deinove receives 30% royalties from sales.

Source: Edison Investment Research

Financials

In its H118 financial results, Deinove reported operating revenue of €715k (vs €140k a year ago), of which €678k were grant payments (for the AGIR programme). Total operating costs amounted to €5.1m and, as previously, the main cost item was salaries and wages at €1.7m vs €1.3m in H117. The net result of -€3.7m was positively affected by tax credits of €661k. Cash burn remained fairly stable and largely in line with our expectations. Our revenue forecasts for in FY18 and FY19 are €728k and €1.12m, respectively, which mainly reflects grant payment and initial sales of cosmetics products in 2019. As discussed in the valuation section above, we see more material revenue stream from the marketed cosmetics products after a period of the roll-out phase over the next several quarters, but admittedly the visibility is currently low. We include sales income from cosmetics ingredients of €314k and €2.0m in FY19 and FY20.

The cash position in H118 was €9.9m, which improved after the share issue in June 2018 raised €8.1m net. In November 2018, Deinove also renewed its equity line financing with Kepler Cheuvreux. The original agreement was established in 2014 and allowed the company to raise

€9.4m before expiring this year. According to the renewed agreement, Deinove can raise up to €12m over the next 36 months (€4m is within an existing mandate and €8m is due to be voted on at the next AGM in 2019).

The financial aid to Deinove of €10.4m from Bpifrance to support the AGIR project consists of repayable advances of €7.7m and €2.7m in grants (booked via P&L). These subsidies will be released over the five year period until 2023 as the programme progresses. The total amount received in 2018 was €2.6m. €2.7m and €2.8m should be received in 2019 and 2020 respectively.

Our operating cost forecasts excluding DNV3837 remain fairly stable, but with a planned Phase II trial for DNV3837, these should increase. We include €12.4m over 2019–2020 and €20.0m over 2021–2022, which is the [industry average](#) for anti-infectives trials. These will be revised once Deinove will announce more concrete study plans. Existing cash, an incoming grant stream and an extended equity line are sufficient to fund existing operations until 2020 and to initiate the Phase II trial for DNV3837. We expect that the next fund-raise will focus significantly on supporting the DNV3837 asset to reach the Phase II readout, which represents an opportunity for value inflection. If the Phase II data is positive, Deinove may explore different alternatives for further development, including raising funds to complete the Phase III trial, which, although capital-intensive, is also most economically rewarding (in case of successful results). Another option would be to partner DNV3837 for the Phase III development, which would require less investment.

Exhibit 11: Financial summary

	€'000s	2016	2017	2018e	2019e
Year end 31 December		IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue		793	214	728	1,120
Cost of sales		0	0	0	(150)
Gross profit		793	214	728	970
EBITDA		(6,362)	(8,521)	(8,950)	(11,982)
Operating profit (before amort. and except.)		(7,676)	(9,681)	(10,131)	(13,308)
Intangible Amortisation		0	(376)	(628)	(562)
Exceptionals		639	296	0	0
Other		0	0	0	0
Operating profit		(7,037)	(9,761)	(10,759)	(13,870)
Net Interest		(31)	(5)	0	0
Profit before tax (norm)		(7,707)	(9,686)	(10,131)	(13,308)
Profit before tax (FRS 3)		(7,068)	(9,766)	(10,759)	(13,870)
Tax		1,115	2,430	1,710	2,640
Profit after tax (norm.)*		(6,897)	(7,256)	(8,422)	(10,668)
Profit after tax (FRS 3)*		(6,258)	(7,336)	(9,049)	(11,230)
Average number of shares outstanding (m)		8.6	10.7	13.5	15.5
EPS - normalised (€)		(0.73)	(0.68)	(0.62)	(0.69)
EPS - (IFRS) (€)		(0.73)	(0.68)	(0.67)	(0.73)
Dividend per share (€)		0.0	0.0	0.0	0.0
Gross margin (%)		N/A	N/A	N/A	N/A
EBITDA margin (%)		N/A	N/A	N/A	N/A
Operating margin (before GW and except.) (%)		N/A	N/A	N/A	N/A
BALANCE SHEET					
Fixed assets		2,336	5,741	6,032	4,944
Intangible assets		201	3,604	4,276	3,714
Tangible assets		1,851	2,044	1,662	1,137
Investments		284	93	93	93
Current assets		11,525	8,400	11,334	4,104
Stocks		0	0	0	0
Debtors		1,792	3,050	2,500	276
Cash		9,316	4,876	8,360	3,353
Other		417	474	474	474
Current liabilities		(2,141)	(2,663)	(2,483)	(3,425)
Creditors		(2,141)	(2,663)	(2,483)	(3,425)
Short-term borrowings		(0)	0	0	0
Long-term liabilities		(10,275)	(10,803)	(12,867)	(14,837)
Long-term borrowings		(9,178)	(9,972)	(12,036)	(14,006)
Other long-term liabilities		(1,097)	(831)	(831)	(831)
Net Assets		1,445	675	2,016	(9,214)
CASH FLOW					
Operating cash flow		(6,327)	(9,346)	(8,262)	(9,227)
Net Interest		(31)	(5)	0	0
Tax		1,115	2,430	1,392	3,050
Capex		(519)	(1,208)	(800)	(800)
Acquisitions/disposals		28	551	(1,300)	0
Financing		437	2,345	10,390	0
Dividends		0	0	0	0
Net cash flow		(5,297)	(5,234)	1,420	(6,977)
Opening net debt/(cash)		(5,435)	(138)	5,096	3,676
HP finance leases initiated		0	0	0	0
Other		0	0	0	0
Closing net debt/(cash)		(138)	5,096	3,676	10,653
Closing net debt/(cash) (Company Definition)		(9,316)	(4,876)	(8,360)	(3,353)

Source: Deinove accounts, Edison Investment Research

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