EDISON

Deinove

Company update

Phase II study with DNV3837 for *C. diff* starts

Pharma & biotech

Deinove reported that the first patient has been enrolled in its Phase II study with a novel quinolonyl-oxazolidinone class antibiotic DNV3837 for moderate to severe *C. diff* infections. The results are expected by the end of 2020, which will be a substantial catalyst for the share price. The company also reported multiple developments in its bioactives portfolio, including a new substantial collaboration with a partner that has experience in commercialising preservative solutions for personal care products. We have slightly increased our valuation to €78m or €4.6/share.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/17	0.2	(9.7)	(0.7)	0.0	N/A	N/A
12/18	0.8	(10.5)	(0.6)	0.0	N/A	N/A
12/19e	1.1	(13.2)	(0.7)	0.0	N/A	N/A
12/20e	2.9	(15.4)	(0.7)	0.0	N/A	N/A

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

First patient in; results expected by end-2020

In January 2020, Deinove announced that the first patient had been enrolled into the ongoing Phase II trial testing its antibiotic DNV3837 for moderate to severe *Clostridioides difficile* (*C. diff*) infections. This is an open-label study that will be conducted in two parts in 15 centres in the US. Part 2 of the study will be randomised in up to 30 patients and will include efficacy endpoints. The results are expected by the end of 2020. The lack of a regulatory approved intravenous treatment option and growing incidence of *C. diff* present a significant opportunity for DNV3837, in our view. DNV3837 is administered intravenously and designed to cross the gastrointestinal barrier, unlike existing IV antibiotics, and target the gut, the site of the infection, more effectively than orally administered antibiotics.

Substantial new bioactives collaboration

In February 2020, Deinove announced that it had signed a memorandum of understanding with Sharon Laboratories, an Israeli group specialising in preservative solutions for the personal care industry. Sharon Laboratories will use Deinove's platform to develop and market a range of new 'bio-based solutions', including bioactives, and the agreement will grant exclusivity to the new partner to access certain Deinove ingredients and R&D capabilities. Disclosed financial details include an immediate payment of $200k, milestone payments and royalties. Even though the relationship is still at the memorandum of understanding stage, we believe that the upfront payment shows Sharon Laboratories' clear intention to progress and finalise the collaboration agreement.

Valuation: €78m or €4.6/share

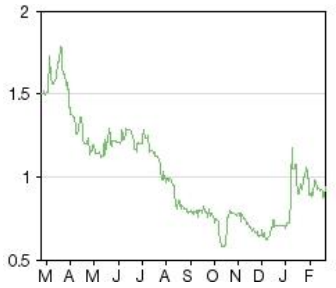
Our risk-adjusted NPV is slightly higher at €78m or €4.6/share vs €72m or €4.2/share previously, mainly due to rolling our model forward. We have already reflected Deinove's H119 results in our model and the FY19 results are due on 2 April 2020. The key catalysts this year are development and commercialisation news from Deinove's bioactives portfolio, the progress of the Phase II trial and final results expected by end-2020.

21 February 2020

Price	**€0.94**
Market cap	**€18m**

Net cash (€m) at end Q219 (excludes conditional government loans of €12.1m)	1.3
Shares in issue	18.9m
Free float	94%
Code	ALDEI
Primary exchange	Euronext Growth
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(2.4)	35.7	(38.9)
Rel (local)	(2.6)	31.2	(47.5)

52-week high/low	€1.79 €0.58

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 in a Phase II trial. Products for other applications, such as cosmetics and nutrition, will support drug development efforts.

Next events

Updates on progress of Phase II trial with DNV3837	2020
Cosmetics ingredient commercialisation updates	2020
Results from the Phase II trial with DNV3837	End-2020

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Edison profile page

Leadership change presents an opportunity

The former CEO Emmanuel Petiot left the company at the end of December 2019, as announced earlier that month. Following our discussions with management, including Mr Petiot before his departure, it is clear that the move was based on his decision to explore new professional opportunities. Mr Petiot was instrumental in steering Deinove to adopt a dual bioactives and pharma R&D business model and Deinove's management reiterated its commitment to both areas. The search for a new CEO is ongoing with the chairman, Dr Charles Woler, acting as interim CEO. We believe this provides an opportunity for Deinove to explore candidates who have a relevant background, in both bioactives and drug development.

Antibiotics: First patient enrolled in Phase II trial

Deinove's most advanced Phase II trial is an open-label study that will be conducted in two parts in 15 centres in the US. In Part 1, 10 patients with moderate to severe *C. Diff* infection will receive DNV3837. The Data Safety Monitoring Board (DSMB) will review the interim results. If the board does not raise any safety issues, Part 2 of the trial will proceed and enrol up to 30 patients with severe *C. diff*, who will be randomized (2:1) to receive DNV3837 or standard of care treatment. The results are expected by end 2020, and will be a substantial catalyst for the share price. If positive, the next step could be a registration Phase III trial. Since DNV3837 is a novel antibiotic, it has obtained a Qualified Infectious Disease Product (QIDP) designation and Fast Track status from the FDA, which will significantly facilitate regulatory interactions.

In our last outlook report, we presented a detailed analysis of the unmet need in *C. diff* treatment and the potential of DNV3837. The lack of a regulatory approved intravenous treatment option and growing incidence of *C. diff* present a significant opportunity for DNV3837, in our view. Antibiotics to treat *C. diff* are mainly given orally (metronidazole could also be given intravenously as a last resort, but that would be off-label use). This means that effective antibiotic treatment of severe *C. diff* is still lacking as oral treatments can struggle to reach the intestines as a result of a patient's pathological condition, while currently available intravenous antibiotics generally 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, unlike existing IV antibiotics, and target the gut, the site of the infection, more effectively than orally administered antibiotics.

Exhibit 1: Deinove's R&D pipeline and product portfolio

Source: Deinove

Bioactives: New collaboration with Sharon Laboratories

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 in the cosmetics and animal nutrition sectors. We reviewed these opportunities in our last published outlook report. Recent new developments include:

- In February 2020, Deinove announced that it had signed **a memorandum of understanding with Sharon Laboratories**, an Israeli group specialising in preservative solutions for the personal care industry. From the details released it appears that Sharon Laboratories' intention is to use Deinove's platform to develop and market a range of new 'bio-based solutions', including bioactives. The agreement will grant exclusivity to the new partner to access certain Deinove ingredients and R&D capabilities. The agreement is expected to be finalised by end-Q120 and the initial term is three years. Disclosed financial details include an immediate payment of $200k, milestone payments and royalties. We believe that while the relationship is only at the memorandum of understanding stage, the upfront payment shows Sharon Laboratories' clear intention to progress and finalise the collaboration agreement. Sharon Laboratories has 40 years of experience in the personal care preservation field, so is clearly an experienced partner. We therefore expect substantial and interesting newsflow from this collaboration in the near term.
- In November 2019, Deinove announced that its **second novel carotenoid** for cosmetics had been previewed at the In-Cosmetics Asia exhibition (the largest regional trade fair) in Bangkok on 5–7 November 2019. Global launch is planned at the In-Cosmetics Global 2020 in

Barcelona, from 31 March to 2 April 2020. Deinove previously said that it planned to launch a second carotenoid, although commercial details are yet to be released.

- The company's first carotenoid product **Phyt-N-Resist (phytoene)** was launched in April 2018. So far, no sales have been booked, which is not surprising as lead times in cosmetic ingredients can be one to two years. In its latest H119 report, Deinove indicated that 'several dozens' of potential customers have been evaluating samples and the first sales could start soon. In January 2020, Deinove announced that it had produced a new 'industrial' batch of Phyt-N-Resist 'to meet the needs of its distributors and future customers', which we interpret as its confidence that sales will materialise in the near future. Phyt-N-Resist is a 100% pure colourless carotenoid that cannot be extracted in pure form from vegetable sources. Carotenoids are known for their antioxidant and anti-ageing properties. Deinove showed that phytoene stimulates laminin production which, like collagen, is a major structural protein in the basal layer (lamina) of the skin (the junction between the epidermis and the dermis). Laminin has been identified as a target for dermatocosmetic applications to promote cellular regeneration and prevent ageing. Univar is taking care of the commercial promotion and distribution of Phyt-N-Resist in the EMEA zone, while Solvay Novecare is marketing it in North America and Asia.

Deinove also has several other bioactive products in its commercial or advanced development portfolio, which we reviewed in detail in our previous reports. We expect more updates on the rest of the cosmetics portfolio in the upcoming FY19 report due on 2 April 2020, or in ad hoc press releases.

Hebelys, an anti-ageing cosmetic ingredient obtained through fermentation of the *Sphingomonas hydrophobicum* bacteria, was developed and a second product launched in collaboration with a French partner, Greentech. Deinove indicated that several cosmetic brands have confirmed their interest and ordered samples to integrate into their brand formulations.

Deinove also has an **animal feed collaboration, COLOR2B,** with Avril, a French agroindustrial group. The two companies have validated the ingredient for animal feed, which will be positioned as a nutrient of biological origin versus other currently available petrochemical products. The product will be marketed as raw material for animal feed. The partners are scaling up manufacturing and preparing to market the first ingredient by end-2020.

In June 2019, Deinove announced **a collaboration agreement with Dow** to develop a new cosmetic ingredient, which selected one extract from Deinove's proprietary bacterial bank. While no further details about the ingredient have been provided, the collaboration is another sign of the external validation of Deinove's expertise in bacterial extracts by a large multinational company. Deinove is responsible for optimisation of the production process, while Dow will be responsible for integrating the ingredient into its portfolio and will have worldwide market exclusivity. The commercialisation is expected to begin in early 2021.

Valuation

Our risk-adjusted NPV is slightly higher at €78m or €4.6/share versus €72m or €4.2/share previously, mainly due to rolling our model forward. This was partially offset after we moved the costs associated with the Phase II trial from 2019 to 2020 (we expected the trial to start las year). As a result, our 2020 EBIT decreased to €15.9m from €12.9m. We maintain all our other assumptions for the R&D projects, as described in our outlook report. The collaboration agreement with Sharon Laboratories seems to have a clear financial benefit in the near (milestones) and mid- to long term (royalties if the products are successful). For the time being, we are not making any adjustments to the bioactives portfolio we included in our valuation, but we will review the collaboration potential again when Deinove releases further details.

We note that as of end-H119 there were unexercised share warrants and options amounting to c 10.7m. However, an absolute majority (8.0m) of those were related to the acquisition of Biovertis/Morphochem. The warrants associated with the latter become exercisable only after certain milestones have been met, which are related to clinical development. Each of these milestones is related to positive R&D developments, which typically provide catalysts for the share price.

Deinove reported cash of €1.9m at the end of H119 and had €12.7m booked as long-term debt (€12.2m is conditional government loans, which are repayable if the products achieve commercial success). In July 2019, Deinove entered into an agreement with the European Select Growth Opportunities Fund to issue a two-year convertible bond with a maximum nominal amount of €15m, 6.5% discount and interest free.

Exhibit 2: DCF valuation of Deinove (operations including ingredients)

(€m)	2020e	2021e	2022e	2023e	2024e	2025e	2026e	2027e	2028e	2029e	2030e
EBIT (risk-adjusted)	(9.8)	(6.1)	(0.1)	3.2	6.1	7.9	8.6	9.8	10.5	11.2	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
D&A	1.9	1.1	1.1	1.1	1.1	1.1	1.1	0.6	0.6	0.6	0.6
Change in WC	0.5	0.1	(0.0)	(1.2)	(2.2)	0.0	(0.1)	(0.1)	(0.1)	0.1	(1.0)
Capex	(0.6)	(0.6)	(0.6)	(0.6)	(0.6)	(0.6)	(0.6)	(0.6)	(0.6)	(0.6)	(0.6)
Operating FCF	**(8.0)**	**(5.6)**	**0.4**	**2.5**	**4.4**	**8.4**	**9.0**	**9.6**	**10.4**	**11.3**	**11.0**
											rNPV (€m)
Free cash flows FY20–30e											14.9
Terminal value (1.5% growth rate assumed)											28.2
Total value											43.1
Valuation/share (€)											**2.5**

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

Product	Launch	Peak sales (€m)	Unrisked NPV (€m)	Unrisked NPV/share (€)	Probability (%)	rNPV (€m)	Value per share (€)
Antibiotics (*C. diff*)	2025	209	146.0	8.5	27.5%	42.2	2.5
Bioactives (DCF)						43.1	2.5
Net cash, last reported						(7.0)	(0.4)
Valuation						**78.3**	**4.6**

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

Exhibit 3: Financial summary

€'000s	2017	2018	2019e	2020e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	214	759	1,120	2,941
Cost of sales	0	0	(150)	(1,000)
Gross profit	214	759	970	1,941
EBITDA	(8,521)	(9,366)	(11,755)	(14,010)
Operating profit (before amort. and except.)	(9,681)	(10,496)	(13,155)	(15,373)
Intangible Amortisation	(376)	(430)	(562)	(511)
Exceptionals	296	172	0	0
Other	0	0	0	0
Operating profit	(9,761)	(10,754)	(13,716)	(15,884)
Net Interest	(5)	(6)	0	0
Profit Before Tax (norm)	(9,686)	(10,502)	(13,155)	(15,373)
Profit before tax (FRS 3)	(9,766)	(10,760)	(13,716)	(15,884)
Tax	2,430	2,014	2,576	3,458
Profit after tax (norm.)	(7,256)	(8,488)	(10,579)	(11,915)
Profit after tax (FRS 3)	(7,336)	(8,746)	(11,141)	(12,426)
Average Number of Shares Outstanding (m)	10.7	13.9	16.3	17.1
EPS - normalised (€)	(0.68)	(0.61)	(0.65)	(0.69)
EPS - (IFRS) (€)	(0.68)	(0.63)	(0.68)	(0.72)
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	5,741	6,923	5,174	3,899
Intangible assets	3,604	4,430	3,714	3,203
Tangible assets	2,044	2,397	1,363	600
Investments	93	96	96	96
Current assets	8,400	9,696	6,029	4,474
Stocks	0	0	0	0
Debtors	3,050	5,212	4,000	4,000
Cash	4,876	3,902	1,555	0
Other	474	582	474	474
Current liabilities	(2,663)	(2,876)	(3,360)	(12,686)
Creditors	(2,663)	(2,876)	(3,360)	(4,274)
Short-term borrowings	0	0	0	(8,412)
Long-term liabilities	(10,803)	(12,247)	(16,776)	(17,046)
Long-term borrowings	(9,972)	(11,677)	(16,206)	(16,476)
Other long-term liabilities	(831)	(570)	(570)	(570)
Net Assets	675	1,496	(8,933)	(21,359)
CASH FLOW				
Operating cash flow	(9,346)	(11,383)	(10,102)	(13,486)
Net Interest	(5)	(6)	0	0
Tax	2,430	2,014	2,619	3,848
Capex	(1,208)	(1,410)	(600)	(600)
Acquisitions/disposals	551	0	0	0
Financing	2,345	8,106	1,208	0
Dividends	0	0	0	0
Net cash flow	(5,234)	(2,679)	(6,876)	(10,238)
Opening net debt/(cash)	(138)	5,096	7,775	14,651
HP finance leases initiated	0	0	0	0
Other	0	0	0	0
Closing net debt/(cash)	5,096	7,775	14,651	24,888

Source: Deinove accounts, Edison Investment Research

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