EDISON

Nuevolution

Q3 results

Clinical development in 2019

Pharma & biotech

Nuevolution's drug discovery platform (Chemetics) continues to receive external validation, with Amgen opting in for another oncology programme from its multi-target collaboration. Transitioning assets to the clinic will be a defining moment for Nuevolution, and the RORγt inhibitor programme (out-licensed to Almirall in psoriatic arthritis and skin conditions) remains on course to potentially enter the clinic in 2019. Nuevolution's internal programmes continue to progress well and new early-stage programmes addressing important inflammation and oncology targets have now been announced (TYK2 and RIPK1). We value Nuevolution at SEK19.7/share.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
06/16	21.3	(151.9)	(4.0)	0.0	N/A	N/A
06/17	120.3	(9.4)	(0.6)	0.0	N/A	N/A
12/18e**	11.5	(109.0)	(2.1)	0.0	N/A	N/A
12/19e**	196.4	75.3	1.0	0.0	16.0	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments. **Year-end has changed to 31 December.

Second opt-in from Amgen collaboration

With the second opt-in in six months, Nuevolution is further demonstrating that it has the in-house ability to execute and deliver on its partnerships. For the two opted-in programmes, all the remaining development costs will be covered by Amgen. If Amgen exercises its option to license a candidate, Nuevolution will receive an initial licensing fee of at least $10m and potential additional milestone payments of up to $400m per candidate. With the collaboration spanning across more undisclosed targets in oncology and neuroscience, significant financial potential exists for Nuevolution.

Positioning the pipeline for an out-licence

Nuevolution continues to build and strengthen its pipeline of preclinical assets and aims to monetise some of those in the near term via out-licensing. It originally guided to a new deal by year-end, but has now suspended this guidance as a result of potential partners taking advantage of it to negotiate more favourable deal terms. We now have no visibility on the timelines for potential new deals for Nuevolution, but believe the BET-BD1 programme, which is nearing candidate nomination (early 2019), is well positioned and most likely to be out-licensed or partnered.

Financials: Funded through key inflection points

For 9M18, revenue remained steady at SEK9.8m (9M17: SEK9.0m), while SG&A rose to SEK22.6m (9M17: SEK17.4m) and R&D costs fell to SEK70.0m (9M17: SEK80.7m), resulting in a net loss of SEK76.1m (9M17: SEK84.9m). As of Q318, gross cash (and equivalents) were SEK130.7m, which should provide runway until H219 assuming there is no further revenue from current or potential future partners.

Valuation: SEK19.7/share (SEK974m)

We value Nuevolution at SEK19.7/share (SEK974m) vs SEK22.8/share (SEK1,127m) previously. The decrease in value is driven by the adjustment of timelines for an expected Amgen out-licence and updating FX rates. We also now include end-September net cash.

10 December 2018

Price	**SEK15.96**
Market cap	**SEK790m**

SEK9.03/US$; US$1.14/€; SEK10.25/€

Net cash (SEKm) at 30 September	127.3
Shares in issue	49.5m
Free float	55%
Code	NUEV
Primary exchange	Nasdaq Stockholm
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	3.9	(0.8)	(8.3)
Rel (local)	10.3	10.5	(1.9)

52-week high/low	SEK20.1	SEK14.06

Business description

Nuevolution is a Copenhagen-based biopharmaceutical company. Its patent-protected Chemetics drug discovery platform enables the selection of drugs to an array of tough-to-drug disease targets. To date it has entered into 17 agreements with major pharmaceutical companies.

Next events

Sign new out-licence/risk-sharing collaboration	2019
Start of Almirall's RORγt Phase I trial	2019

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Edison profile page

Chemetics continues to strengthen pipeline

Nuevolution's business model embodies continuous revenue generation and risk mitigation, executed through a 'multiple shots on goal' approach to drug development. Underpinning this is the internally developed DNA-encoded drug discovery platform, Chemetics, which comprises compound libraries (of up to 40 trillion molecules) that have been designed to rapidly select drugs for an array of 'tough-to-drug' targets. The company has a number of late-stage preclinical assets, alongside more than 10 earlier-stage programmes (varying from hit identification to hit optimisation). In the Q3 results, Nuevolution disclosed that it has identified and is developing small molecule inhibitors for TYK2 and RIPK1, which are 'hot targets' in drug discovery. While in the near term we believe that later-stage assets (eg RoRγt and BET-BD1) will continue to be core candidates for out-licensing, we believe these two new programmes will present strong out-licensing/ partnering opportunities as they progress towards candidate nomination. For more detail on the complete pipeline, please refer to our previous note, Pipeline and partnerships continue to strengthen.

TYK2: Not just another kinase

Tyrosine kinase 2 (TYK2) is a member of the Janus kinase (JAK) family, which sits downstream of cytokine receptors and mediates inflammatory signalling. Inhibition of the JAK family is a proven strategy for the treatment of inflammatory disorders, notably as evidenced by Pfizer's JAK inhibitor Xeljanz (tofacitinib), which generated global sales of $1.2bn in 9M18 across rheumatoid arthritis, psoriatic arthritis and ulcerative colitis. To date, there are no marketed TYK2 inhibitors, but there have been some noteworthy clinical-stage compounds under investigation as oral-based treatments for patients with moderate to severe plaque psoriasis (PsO). The most advanced compound in the clinic is a selective oral TYK2 inhibitor from Bristol-Myers Squibb (BMS-986165), which recently embarked on two pivotal Phase III trials (POETYK-PSO-1 and POETYK-PSO-2) following strong Phase II data reported in September 2018. BMS-986165 was shown to achieve PASI 75 (75% reduction in the psoriasis area and severity index) in 67–75% of patients in the 3mg, twice daily and higher dose groups, compared to 7% for placebo at week 12. Efficacy was observed regardless of previous treatment with a biologic.

With several other programmes in Nuevolution's pipeline also being developed for PsO (RORγt, IL-17A and BET-BD1), it will likely be able to drawn on its growing preclinical experience in this indication to identify a clinical candidate quickly. We anticipate that Nuevolution's TYK2 programme will generate significant external interest as it advances and, while an out-licence in 2019 is unlikely, potential deals in 2020 could materialise if attractive deal terms are presented to Nuevolution by possible partners.

RIPK1: Playing a pivotal role in neuroinflammation

Receptor-interacting serine/threonine-protein kinase 1 (RIPK1) is a signalling kinase in the tumour necrosis factor receptor (TNF) pathway, and acts to regulate inflammation and cell death in tissues throughout the body. It plays a role in a range of inflammatory diseases and is of particular interest in the neuroinflammatory processes thought to drive some neurodegenerative disorders. Notably, RIPK1 has recently been implicated in the progression of Alzheimer's disease (AD), where it is believed that RIPK1 mediated signalling causes the accumulation of amyloid plaques.

RIPK1 is an attractive target in drug discovery and Nuevolution is likely to gain external interest as its discovery programme progresses. Denali Therapeutics announced in November 2018 that it had partnered with Sanofi on its RIPK1 inhibitors (DNL747 and DNL758), with an upfront fee of $125m and milestones (development and commercial) that could exceed $1bn. Importantly, Phase I data

indicated that DNL747 was safe and well-tolerated in healthy subjects, and has now progressed into two Phase Ib safety and pharmacokinetic studies in patients with Alzheimer's disease (AD) and amyotrophic lateral sclerosis (ALS). As part of the deal, Sanofi will cover the remaining costs of all Phase Ib and II trials, with Denali covering 30% of any Phase III trial costs.

Amgen and Almirall: 2019 a year of inflection points

In July 2018, Amgen exercised its right to opt in on the first of at least three undisclosed programmes (multi-target collaboration across oncology and neuroscience), and has assumed responsibility for all further costs incurred by both parties. In November 2018, Amgen exercised its right to option a second programme. Nuevolution currently retains the ownership of both these programmes. The multi-target collaboration is structured as follows for each programme:

- Early-stage discovery: Nuevolution covers all costs.
- Proof of concept: Amgen confirms activity in animal models.
- Contractual opt-in: Amgen covers all costs including those of Nuevolution, with shared development of the programme.
- Amgen in-licenses the programme.

Should Amgen exercise its option to license a candidate from either programme before the end of Phase I, Nuevolution will receive, per programme, an initial licensing fee of at least $10m, clinical and commercial milestone payments (of up to $400m in total depending on project success), and subsequent royalties on sales if commercialised.

The targets have not been disclosed for either of the opted-in programmes and Nuevolution does not expect either programme to produce clinically ready compounds until at least late 2020. We currently forecast that Amgen will in-license both opt-in programmes before they enter Phase I development (the first in 2019 and the second in 2020). However, a later opt-in for either would increase the size of any potential licensing payment, as per the agreement in place. Additionally, Nuevolution has a third programme in early-stage development.

In our view, the Almirall RORγt inhibitor programme is likely to enter the clinic in 2019 (forecast c SEK70m payment on the start of Phase I clinical trial) and will trigger the start of payments to Nuevolution, which could increase to €172m in development and regulatory milestones (€270m in tiered commercial sales milestones will also be available if the product is commercialised). The timing and design of any clinical trial is ultimately Almirall's decision and we await further information on these elements.

We note that milestone payments from Almirall and Amgen remain a key sensitivity in our valuation for Nuevolution, and any difference from our forecasts in the size or timing of payments would materially affect our valuation.

Financials

Revenue for the first nine months of FY18 remained steady at SEK9.8m (9M17: SEK9.0m), driven primarily by the ongoing partnerships with Janssen and Amgen. With Amgen now opted in for two assets in its collaboration with Nuevolution, we anticipate an ongoing revenue stream for reimbursement of Nuevolution's incurred R&D costs.

We now forecast significantly reduced FY18 revenue of SEK11.5m compared to SEK112.6m previously, due to pushing back our forecasts for Amgen to in-license an asset in 2019 compared with 2018 previously. We note that there is significant sensitivity around our forecast revenue streams as we have limited visibility on the progress of the Amgen, Almirall and Janssen

partnerships. We currently assume that Almirall will enter the clinic in 2019 with its licensed RORγt inverse agonist and forecast that this will trigger a substantial milestone (c SEK70m) for Nuevolution. Additionally, we forecast that Amgen will in-license an asset in 2019 to the approximate value of SEK100m and that the Janssen partnership will contribute c SEK16m to Nuevolution's revenue stream.

SG&A rose to SEK22.6m (9M17: SEK17.4m), primarily as a result of up-listing to the Nasdaq Stockholm main market in June. We forecast an increase in FY18 SG&A costs to SEK29.0m (vs SEK25.3m previously) and a reduction beyond 2018. R&D costs fell to SEK70.0m (9M17: SEK80.7m) as expensive toxicology studies for the BET-BD1 and RORγt near completion. We have decreased our FY18e R&D costs to SEK90.4m (vs SEK109.7m previously).

Net loss reduced to SEK76.1m (9M17: SEK84.9m). We now forecast an FY18 net loss of SEK102.4m (vs SEK13.6m previously). As of 30 September 2018, gross cash and cash equivalents were SEK130.7m (30 September 2017: SEK146.4m), which should provide runway until H219, assuming no further milestone revenue from Almirall, Amgen and Janssen in addition to any potential upfront from new potential partners.

Although Nuevolution has changed its financial year end to 31 December (from 30 June), we retain a 30 June year-end in our model for historic numbers, but have altered our forecasts to take into account the new year-end. Once Nuevolution has reported a full year under the new format, we will update our historic financials.

Valuation: SEK19.7/share (SEK974m)

We value Nuevolution at SEK19.7/share (SEK974m) vs SEK22.8/share (SEK1,127m) previously. Our reduced valuation is predominately driven by pushing back potential Amgen in-licenses. We now forecast that three Nuevolution/Amgen programmes are in-licensed by Amgen in 2019, 2020 and 2021, and assume that Nuevolution incurs no further R&D costs for the two opted-in Amgen programmes (according to the terms of the partnership agreement). We note that the progress in the Amgen partnership remains positive, although limited visibility remains on any potential in-license(s) timelines by Amgen. We now believe our new forecast in-license dates for Amgen are more in line with the development of the three assets to date. However, we note Amgen could in-license these programs earlier or not at all, adding respectively potential upside or downside to our valuation.

However, we note that Nuevolution will incur direct R&D costs for these programmes and will be reimbursed separately by Amgen. Our R&D forecasts therefore still include this forecast spend. We assume no other changes in development timelines and all other assumptions remain the same. For details of our valuation methodology for Amgen, please see our outlook report, Pipeline and strategic execution drives prospects, published on 15 March 2018. We have rolled forward our model, and updated for end-September cash (SEK127.3m) and FX rates. Please note that we have corrected for an $:€ exchange rate error in our previously published note, which in particular negatively affected the contribution Almirall makes to our valuation. Our underlying assumptions remain unchanged.

Our valuation of SEK974m, including net cash of SEK127.3m, is based exclusively on a risk-adjusted model of the future milestones we expect from the Almirall (SEK9.1 per share), Amgen (SEK7.5 per share) and Janssen (SEK0.4 per share) deals (ie excluding any value from the technology itself, other pipeline assets and excluding future deal opportunities), using a 12.5% discount rate. We have not ascribed value at this point to the unique platform and multiple candidates at early stages of preclinical development. We note that the ability to attract and secure

deals for these assets will be key to the evolution into a profitable operation and that any new deals would add upside to our current valuation.

Exhibit 1: Sum-of-the-parts NPV

Product	Partner	Indication	Phase	NPV of milestone payments (SEKm)	rNPV of milestone payments (SEKm)	NPV of royalties on sales (SEKm)	rNPV of royalties on sales (SEKm)	Total rNPV (SEKm)	Total rNPV/ share (SEK)
RORγt inhibitor	Almirall	Psoriasis & PsA	Preclinical	1251.7	284.0	1672.1	167.2	451.2	9.1
Various	Amgen	Oncology & neuroscience	Drug discovery	742.3	373.7	0.0	0.0	373.7	7.5
	Janssen	Anti-infective	Drug discovery	49.2	21.9	0.0	0.0	21.9	0.4
Net cash (at 30 September 2018)								127.3	2.6
Valuation								974.1	19.7

Source: Edison Investment Research

Exhibit 1: Financial summary

Accounts: IFRS, Year-end: June, SEK000s	2016	2017	2018e	2019e
INCOME STATEMENT				
Total revenues	21,314	120,318	11,477	196,393
Reported gross profit	21,314	120,318	11,477	196,393
SG&A (expenses)	(57,493)	(23,216)	(29,020)	(26,989)
R&D costs	(115,707)	(107,587)	(90,373)	(94,892)
Adjusted EBIT	(151,886)	(10,485)	(107,916)	74,513
Reported EBIT	(151,886)	(10,485)	(107,916)	74,513
Finance income/(expense)	(22)	1,045	(1,056)	782
Adjusted PBT	(151,908)	(9,440)	(108,971)	75,294
Reported PBT	(151,908)	(9,440)	(108,971)	75,294
Income tax expense	6,911	(16,046)	6,538	(26,353)
Adjusted net income	(144,997)	(25,486)	(102,433)	48,941
Reported net income	(144,997)	(25,486)	(102,433)	48,941
Earnings per share				
Basic EPS (SEK)	(4.0)	(0.6)	(2.1)	1.0
Diluted EPS (SEK)	(4.0)	(0.6)	(2.2)	1.0
Adjusted basic EPS (SEK)	(4.0)	(0.6)	(2.1)	1.0
Adjusted diluted EPS (SEK)	(4.0)	(0.6)	(2.2)	1.0
Average number of shares - basic (m)	36.5	42.9	45.9	49.5
Average number of shares - diluted (m)	36.5	43.3	46.8	46.8
Number of shares outstanding -end period (m)	42.9	42.9	49.5	49.5
BALANCE SHEET				
Property, plant and equipment	5,494	5,538	5,761	5,973
Other non-current assets	8,585	6,397	13,527	1,665
Total non-current assets	14,079	11,935	19,288	7,638
Cash and equivalents	205,955	179,595	100,288	166,418
Trade and other receivables	367	93	93	93
Other current assets	14,564	10,032	9,730	3,192
Total current assets	220,886	189,720	110,111	169,703
Non-current loans and borrowings	3,482	2,939	2,939	2,939
Total non-current liabilities	3,482	2,939	2,939	2,939
Trade and other payables	12,162	10,986	6,592	6,592
Current loans and borrowings	1,222	1,482	1,482	1,482
Other current liabilities	20,044	16,286	11,403	10,403
Total current liabilities	33,428	28,754	19,477	18,477
Equity attributable to company	198,055	169,962	106,984	155,925
CASH FLOW STATEMENT				
Profit before tax	(151,908)	(9,440)	(108,971)	75,294
Depreciation of tangible assets	1,328	1,703	277	288
Share based payments	48,528	(153)	0	0
Other adjustments	22	(1,045)	1,056	(782)
Movements in working capital	19,594	(962)	(8,568)	0
Net cash from operating activities (pre-tax)	(82,436)	(9,897)	(116,207)	74,801
Interest paid/received	(224)	(798)	(1,056)	782
Income taxes paid	1,210	(12,520)	0	(7,953)
Cash from operations (CFO)	(81,450)	(23,215)	(117,262)	67,630
Capex (includes acquisitions)	(504)	(715)	(500)	(500)
Other investing activities	(51)	(9)	0	0
Cash used in investing activities (CFIA)	(555)	(724)	(500)	(500)
Net proceeds from issue of shares	242,061	0	104,292	0
Other financing activities	(1,119)	(1,253)	(1,000)	(1,000)
Cash from financing activities (CFF)	240,942	(1,253)	103,292	(1,000)
Increase/(decrease) in cash and equivalents	158,937	(25,192)	(14,470)	66,130
Cash and equivalents at beginning of period	46,250	205,955	114,758	100,288
Cash and equivalents at end of period	205,955	179,595	100,288	166,418

Source: Company accounts, Edison Investment Research. Note: historical financials have a 30 June year-end. Forecasts have a 31 December year -end.

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