

Nuevolution

Pipeline and strategic execution drives prospects

Nuevolution's 2017 was defined by internal progress of the RORyt inhibitor and BET-BD1 programmes (expected to be clinically ready in 2019). In 2018 we anticipate value will be driven by new and existing partners, for example we expect Almirall to initiate a RORyt inhibitor Phase I trial in late 2018, making it the first Nuevolution product candidate to enter the clinic. In addition to existing collaborations, a new partnership is anticipated by Nuevolution in the next three to nine months. If achieved, revenue from these events will aid Nuevolution's strategy of transitioning into a clinical stage biotech. We value Nuevolution at SEK21.0/share or SEK901m from SEK21.4/share (SEK917m) previously.

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
06/18e	104.9	(32.1)	(0.5)	0.0	N/A	N/A
06/19e	229.2	87.6	1.3	0.0	13.5	N/A

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

Major year for Almirall and Amgen partnerships

In 2018, we anticipate significant newsflow from partnerships with Almirall's RORyt inhibitor (licensed from NUE in Psoriatic arthritis and dermatology) potentially entering the clinic, while Amgen could exercise its option this year to further develop one of the partnered oncology programmes. Both events would likely trigger substantial milestone payments. Additionally, a new deal is expected shortly, potentially focused on the BET-BD1 or RORyt inhibitor programmes.

Clinical readiness in 2019 is a key goal

Nuevolution has selected lead indications for its retinoid-acid receptor-related orphan receptor gamma t (RORyt) inhibitor (outside of Almirall's selected indications) and BET-BD1 programmes with the aim that both are clinically ready in 2019. These are significant milestones as its aim is to transition from a pure platform play into a clinical stage biotech company. Lead development in the RORyt inhibitor programme will be in ankylosing spondylitis while BET-BD1 will be in atopic dermatitis and/or psoriasis. The three markets are respectively anticipated to be worth approximately \$2bn, \$6bn and \$20bn by 2022 (EvaluatePharma).

Financials: Costs in line with expectations

For the period 1 July to 31 December 2017, R&D costs increased slightly to SEK52.7m (2016: SEK52.3m) and we expect this trend to continue in 2018. SGA increased to SEK16.7m (2016: SEK12.4) as a result of one-off costs for the impending Nasdaq main market up-listing. Net cash of SEK110.6m (gross cash: SEK114.8m) should be sufficient for Nuevolution to operate into 2019.

Valuation: SEK21.0/share (SEK901m)

We value Nuevolution at SEK21.0/share (SEK901m) This decrease is a result of a reduction in net cash, a delay in the expected start of the Almirall Phase I and updating for FX rates, offset by the rolling forward of our model.

FY17 report

Pharma & biotech

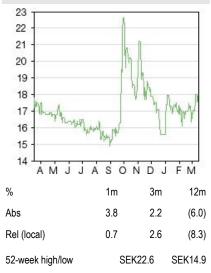
15 March 2018

PriceSEK17.58Market capSEK754mSEK8.25/1US\$; 1.23US\$/1EUR; 10.19SEK/1EURNet cash (SEKm) at 31 December 2017Shares in issue42.9mFree float13.4%CodeNuEVPrimary exchangeNasdaq First North Fremier

N/A

Share price performance

Secondary exchange



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

Up-list to Nasdaq Stockholm main market	June 2018
Sign new out-licence/risk-sharing collaboration	2018
Move one programme into the clinic	2019
Analysts	

Analysis	
Dr Daniel Wilkinson	+44 (0)20 3077 5734
Dr Susie Jana	+44 (0)20 3077 5700

healthcare@edisongroup.com

Edison profile page

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Investment summary

Company description: Targeting what others cannot

Nuevolution is a Scandinavia-based leader in small molecule drug discovery, co-founded in 2001 by CEO Alex Haahr Gouliaev. The company's internally innovated DNA-encoded drug discovery platform, Chemetics, has been designed to rapidly select drugs for an array of tough-to-drug disease targets; the technology has been validated by multiple collaborative deals, notably the deals in 2016 with Amgen and Almirall. In addition to out-licensing deals, Nuevolution is developing an early-stage portfolio of drugs that it intends to take to the clinic. Nuevolution's headquarters are in Copenhagen, Denmark, and it employs 47 people (as of 31 December 2017). To date, the company has generated approximately SEK530m in revenues through collaborations and raised net proceeds of SEK230.1m from its IPO on Nasdag First North Premier in Stockholm, Sweden.

Valuation: Amgen, Almirall and Janssen form basis of our rNPV

We value Nuevolution at SEK21.0/share (SEK901m) compared with SEK21.4/share (SEK917m) previously. This decrease is predominately due to our updated FX rates and the delay in when we anticipate the Almirall Phase I trial to start – we now forecast it to start in late 2018 (the first half of FY18/19 – 30 June year end). We note a reduction in net cash, however this has been mainly offset by the rolling forward of our model. Our valuation of SEK901m including net cash of SEK110.6m is based exclusively on a risk-adjusted model of the future milestones we expect from the Almirall (SEK9.7 per share), Amgen (SEK8.3 per share) and Janssen (SEK0.4 per share) deals using a 12.5% discount rate. We note near-term milestones are a core driver of our valuation, any change in the timing or size of these from our assumptions will have a material effect on our valuation. We have not ascribed value at this point to the unique platform and multiple early stage candidates.

Sensitivities: Clinical validation is the long term focus

Nuevolution is subject to drug development risks, including clinical development delays or failures; however, the company's 15+ compounds in parallel development helps to reduce the risk typically associated with pure-play biotechs. Additional sensitivities exist around IP protection, regulatory risks, competitor successes, partnering setbacks and financing and commercial risks. While Nuevolution's strategy minimises the business risk associated with drug development by partnering early on in development, general risk remains in the partner's willingness to progress these partnerships. One of the key sensitivities for Nuevolution is the successful transition of molecules discovered by its Chemetics programme into clinical-stage development, which would enable further validation of its technological capabilities. Financing needs depend on milestone revenues from existing partners and potential new partnering activities – delay or failure to receive future milestones would generate a funding gap during FY18/19.

Financials: Dependent on milestones and deals

While we note that Nuevolution has changed its financial year end to 31 December, we retain in our model a 30 June year end. Any reference to FY refers to a 30 June year end and we will alter our reporting once Nuevolution has reported a full year under the new format. For the six-month period of 1 July to 31 December 2017, revenues were SEK4.8m, a reduction on the previous period (SEK112.8m) in 2016 which benefited from the SEK109.2m Almirall upfront payment. R&D costs increased slightly on the previous year to SEK52.7m (2016: SEK52.3m), while SGA increased to SEK16.7m (2016: SEK12.4) as a result of one-off costs for the impending Nasdaq main market uplisting. Net cash of SEK110.6m (gross cash: SEK114.8m) should be sufficient for Nuevolution to operate into FY18/19 without need for additional revenue. We forecast significant near-term revenues from the Amgen and Almirall deals, with our model forecasting that Amgen will exercise its option on one of the programmes before the end of June (end of FY17/18 financial year). This



Amgen payment makes up the majority of our revenue in this financial year (FY17/18) and either failure to achieve this or changes to the timing/size of the payment would have a material effect on our forecasts.

Outlook: Impressive execution gives confidence

Since our initiation of coverage (<u>Chemetics proof is in the deal making</u>) in February 2017, Nuevolution has continued to advance its internal pipeline to value inflection points, notably clinical readiness of its two lead programmes (RORyt and BET-BD1 inhibitors). These compounds, in addition to the rest of the pipeline, were identified through its proprietary Chemetics platform which enables the rapid development of small molecule drugs for 'tough-to-drug' targets. It has proven to have considerable appeal to the global pharmaceutical industry as it battles to improve R&D productivity, most recently highlighted by deals with Almirall and Amgen. While Nuevolution's historic strategy has been to leverage the platform to generate compounds for partners, the longterm strategy is to evolve from a platform-based biotech to a clinical biotech. As such, the near-term goal remains the creation of a stable revenue stream through partnerships which can support the long-term development of Nuevolution's wholly owned assets.

Nuevolution has now selected priority indications for the lead programmes which it expects to be clinically ready in 2019. The RORyt inhibitor's lead development will be in ankylosing spondylitis while in the BET-BD1 programme, the priority indication will be atopic dermatitis/psoriasis. In addition to its lead candidates, Nuevolution continues to advance the rest of it internal pipeline which includes 10+ programmes, though many remain undisclosed at this time.

Nuevolution's partnerships and collaborations with Almirall, Amgen and Janssen continue as expected. In 2018, we continue to predict that Almirall moves the RORyt inhibitor into the clinic (in dermatology and psoriatic arthritis indications) and Amgen takes up the option on the first product candidate to emerge from the Nuevolution collaboration. Nuevolution has recently restated its timelines for another out license or partnership deal, which they expect to occur within 3-9 months.

We believe fruition of some if not all of these aforementioned milestones (Almirall into clinic, Amgen option taken and new out licensing deal) would enable Nuevolution to advance its own pipeline into clinical development potentially without the need for further capital (either as equity or debt). Finally we note that Nuevolution continues to expand its investor base and in the short term (before 30 June 2018) will up-list to Nasdaq Stockholm's main market.

Pipeline overview: Clinical development in sight

Nuevolution has numerous publicly announced programmes alongside up to 10 earlier-stage undisclosed programmes in various stages from screening to hit validation and early hit optimisation. Of the main pipeline, the RORyt inverse agonist and the BET-BD1 programmes are the most advanced: earlier-stage assets including cytokine X and GRP78 continue to progress well. Based on Nuevolution's own guidance, we anticipate the RORyt inverse agonist and the BET-BD1 programmes will be ready to enter the clinic in 2019 following the successful completion of IND-enabling studies. Exhibit 1 highlights Nuevolution's development pipeline.



Indication	Stage	Target	Ownership	Notes
Chronic inflammatory diseases	Preclinical	RORyt inverse agonist	Partner Almirall in dermatology and psoriatic arthritis.	RORyt plays an important part in the generation of mature T-cells and the subsequent production of cytokines, notably IL-17. IL-17 is a key pro- inflammatory cytokine that plays a role in multiple inflammatory and autoimmune conditions and in certain circumstances cancer. Injectable antibodies against IL- 17 have demonstrated good efficacy for treatment of psoriasis in humans. Nuevolution's RORyt inverse agonists are oral-based therapeutics that offer the ability to down regulate IL-17. The lead candidate is partnered with Almirall for dermatology and psoriatic arthritis. Clinical development in dermatology is expected to commence in 2018.
			Other indications 100% ownership NUE	Nuevolution retains rights to other non-dermatological indications. Ankylosing spondylitis (AS) is the priority indication with inflammatory bowel diseases (IBD) as a secondary. Completion of Kg scale-up is expected shortly with in vivo efficacy in AS mouse model anticipated in H118. IND-enabling studies are anticipated to start in Q218 with clinical readiness by early 2019 possible.
Inflammatory diseases	Discovery: lead optimisation	BET bromodomain inhibitors	100% ownership NUE	The BET sub-family of bromodomains is a novel biological disease target class offering a new mode of action for treatment of cancer and inflammatory diseases. Atopic dermatitis (AD) and/or psoriasis have been selected as the primary indication with secondary indications in fibrosis (Scleroderma) and systemic lupus erythematosus. The nomination of a lead candidate is expected to occur during Q218 with the programme potentially reaching clinical readiness by mid-2019.
Inflammatory diseases	Discovery: hit- to-lead	Cytokine X	100% ownership NUE	The cytokine X (target undisclosed) programme continues to optimise lead product candidates. In H217, a NUE selected molecule demonstrated comparable efficacy to that of an antibody for the same target in a mouse model. The cytokine X programme looks to offer tablet-based replacement for currently available but costly injectable medicines.
Cancer	Discovery: hit- to-lead	GRP78	50% ownership*	GRP78 is a member of the chaperone family of proteins; it is over expressed in many tumour types including breast cancer and brain tumours. Selected compounds are now in the control of CRT/ICR and further progression is reliant on them.
Cancer	Discovery: hit optimisation	RORγt agonist (inhibition)	100% ownership NUE	RORyt agonists may provide the immune system with a novel tumour attacking mechanism. Nuevolution continue to probe the mechanism of action for its lead product candidates.
Various	Discovery: various	Various	100% ownership NUE	10+ discovery programmes in a range of undisclosed indications including oncology, inflammatory diseases and immuno-oncology.

Exhibit 1: Nuevolution's development pipel

Source: Nuevolution, Edison Investment Research. Note: *Collaboration with CRT and ICR.

RORyt inverse agonist: Focus on ankylosing spondylitis

RORyt is an important master control switch of immune system activation and a potential novel target for the treatment of autoimmune diseases (by immune suppression) and cancer immunotherapy (by immune activation). RORyt plays a critical role in the generation of mature T-cells, particularly Type 17 effectors that produce an array of cytokines, notably IL-17A (IL-17A enables the recruitment of key immune components to sites of inflammation).

Nuevolution has retained the rights to develop the RORyt inverse agonist (inhibitor) in indications not covered by the Almirall deal and has chosen ankylosing spondylitis (AS) as a lead indication with inflammatory bowel disease (IBD) as a secondary indication. Nuevolution expects to complete kg production of the active pharmaceutical ingredient (API) in Q118 which should enable the start of investigational new drug (IND) enabling safety studies in Q218. Following satisfactory completion, Nuevolution would be in a position to submit an IND application to the US FDA, or Clinical Trial Application (CTA) to EMA, potentially preparing for clinical development by early 2019. Targeting of IL-17 in the treatment of AS has been validated by the approval of Novartis' Cosentyx (secukinumab) which remains the only IL-17 approved antibody in AS. However, we note this could quickly change, as Lilly's IL-17 antibody Taltz (ixekizumab) has recently reported top-line positive Phase III results in radiographic axial spondyloarthritis (a broader definition of patients then AS that includes patients with or without characteristic inflammatory changes in the sacroiliac joints) and



plans to submit for regulatory approvals later in 2018. A RORyt inhibitor which plays a critical upstream role in preventing the generation of IL-17 producing T-cells should, in theory, be able to produce a comparable effect to these antibodies although this has yet to be clinically validated.

Ankylosing spondylitis: Large, unmet commercial opportunity

Ankylosing spondylitis (AS) is a chronic inflammatory arthritis predominately affecting the spine and sacroiliac joints. Over the course of time chronic inflammation of the spine (spondylitis) can lead to a complete fusion of the vertebrae (ankyloses) and loss of mobility of the spine. AS is associated with systemic manifestations such as neurological, renal and cardiovascular disease.

Spondyloarthritis refers to a group of inflammatory diseases that cause arthritis or joint inflammation. AS is the most common but other types include psoriatic arthritis, reactive arthritis, enteropathic arthritis and juvenile enthesitis related arthritis. 90% of individuals diagnosed with ankylosing spondylitis are HLA- B27 (human leukocyte antigen - B27) gene positive. However, it is not the sole driver of the disease as the majority of patients who are HLA-B27 do not go on to develop AS. Those that do are known to have an earlier onset in comparison with those who are HLA-B27 negative.

Prevalence varies by country and is correlated to HLA B27 gene; the higher the HLA-B27 prevalence the higher the AS prevalence; there is great variability between ethnic, racial and geographic variation (David and Lloyd 1999). The <u>prevalence</u> of ankylosing spondylitis is 0.1% to 1.4%, depending on the population studied.

Medical management of AS has historically been centred on symptomatic treatment to reduce pain and inflammation (eg NSAIDS, sulfasalazine, methotrexate, corticosteroids). The advent of biologic therapies has led to the approval of treatments that target pro-inflammatory excess cytokines. Approved treatments include:

- TNF-inhibitors: Humira (adalimumab), Remicade (infliximab), Simponi (golimumab), Cimzia (certolizumab) and Enbrel (etanercept).
- IL-17 inhibitors: Cosentyx (secukinumab)

Novartis' Cosentyx (secukinumab) is the first and thus far only IL-17 inhibitor approved for AS. It received FDA approval in January 2016. It is an IL-17 inhibitor (antibody IV treatment) that is also approved for PsO (psoriasis) and PsA (psoriatic arthritis). Novartis reported combined sales of \$2.1bn across all three indications in FY17, its second full year of launch. Cosentyx offers an alternative treatment option for patients who are not responding to TNF-inhibitors or are unable to cope with their side-effect profiles. However, like the TNF-inhibitors, it carries a risk of increased infections. In clinical trials, it was shown to exasperate or cause new inflammatory bowel disease in a very small proportion of patients.

If a RORyt inhibitor is to succeed both clinically and commercially it will likely need to demonstrate comparable efficacy and safety to that of Cosentyx. In its registration studies, Cosentyx demonstrated a 33% absolute improvement over placebo (61% vs 28%) in the number of patients who had an ASAS20 response, which is defined as a patient who has had an improvement of 20% in at least three of either: patient global assessment, pain assessment, function and inflammation. It additionally demonstrated a 25% absolute improvement over placebo (36% vs 11%) for the number of patients who achieved an ASAS40 response (defined as ASAS20 but for a 40% response). On the back of Cosentyx's success and the likely approval of Lilly's Taltz in AS later this year, we believe that Nuevolution's RORyt small molecule oral inhibitor (that operates upstream of IL-17) could have a significant place in the market if it provides comparable efficacy and safety.

On consensus estimates (EvalutePharma) the total worldwide market is worth potentially \$2.2bn by 2022, up c 38% vs 2016 sales of \$1.6bn. The majority of this value is expected to continue to be driven by blockbuster biologics Humira (AbbVie) and Cosentyx (Novartis). Novartis estimates that in



the US alone there are currently 1.13m patients with AS, of which roughly half are diagnosed (520,000). Of those diagnosed, 85% go onto treatment (440,000) while a further 19% of these ultimately end up receiving biologics (84,000). In our view, the market would be very receptive to a competitively priced oral RORyt inhibitor that has comparable efficacy and safety to IL-17 antibodies. The ability to capture a small percentage of this market could be transformational for a company of Nuevolution size. However, we note any such sales are at least several years off, assuming any compound is clinically successful.

Competitive RORyt inverse agonists interest focused on psoriasis

We have reanalysed and updated our overview of the RORyt inverse agonists competitor space (Exhibit 2). Multiple competitors continue to advance, however, most are predominately focused on psoriasis indication (please see our previously published initiation note <u>Chemetics proof is in the</u> <u>deal making</u> for a detailed description of the disease) which could enable Nuevolution to gain ground in AS and IBD. However, we note success for Nuevolution in these indications would validate both target and indication and would likely lead to increased competition.

While Nuevolution's internal focus is on AS and IBD, the out licensing of Nuevolution's RORyt inverse agonists to Almirall in psoriatic arthritis and dermatological indications means Nuevolution will likely have an indirect presence in the psoriasis indication. However, Almirall's exact clinical indication has not yet been announced publically, although we expect the company to provide an update this year.

One of the most advanced RORyt inverse agonists is AGN-242428 in Phase II development by Allergan (through the acquisition of Vitae Pharmaceuticals for \$639m in cash). Allergan has initiated a RORyt <u>Phase II study in psoriasis</u> and a Phase III trial is expected to initiate in 2020. In May 2016, Vitae Pharmaceuticals reported top-line results from its Phase IIa clinical trial testing its small molecule RORyt inverse agonist (VTP-43742) in psoriatic patients. In the low dose cohort (350mg), VTP-43742 reported a 23% improvement in the Psoriasis Area and Severity Index (PASI) score at day 28 from baseline (p<0.015), which compared favourably to a 1% deterioration for patients on placebo. Patients on the higher dose cohort demonstrated a 29% improvement from baseline at day 28 (p=0.003). There were no reported serious adverse events at all dose levels. At the highest dose tested (700mg), reversible transaminase elevations (results in liver toxicity) were observed in 5/34 patients. No dose limiting toxicities were seen in any of the Phase Ia, Ib and IIa trials. In the Phase Ib trial, some nausea and headache were observed at the maximum dose of 1,400mg, although it was not dose limiting. These are the first Phase II data to confirm the validity of RORyt as a drug target for the treatment of psoriasis.



Exhibit 2: RORyt inverse agonists in development								
Drug	Company/partner	Delivery	Status	Indication(s)	Notes			
Development programme	Nuevolution/ Almirall	Oral	Preclinical	dermatology and	, , , , , , , , , , , , , , , , , , ,			
AGN-242428	Allergan	Oral	Phase II	Psoriasis	Allergan, through the acquisition of Vitae Pharmaceuticals for \$639m, is developing AGN-242428, an oral RORyt inverse agonist (previously known as VTP-43742). In an ongoing <u>Phase II trial</u> which is expected to read out in September 2019.			
GSK-2981278	GSK	Topical	Phase II	Psoriasis	Has completed a Phase II and Phase I trial for the topical treatment of plaque psoriasis. At its Q217 results (and confirmed recently at FY17 results), GSK announced it will terminate, partner or divest GSK-2981278.			
AZD-0284	AstraZeneca	Oral	Phase I	Psoriasis	Phase I study in plaque psoriasis vulgaris has completed in healthy patients. A <u>Phase I</u> ongoing in moderate to severe psoriasis patients with data expected in the summer. The trial is a randomised, double blind, placebo controlled study and is expected to enrol 25 patients with initial data expected in the summer.			
ARN-6039	Arrien Pharmaceuticals/ Boston Pharmaceuticals	Oral	Phase I	Autoimmune disorders	In June 2017, Arrien announced a worldwide licence agreement with Boston Pharmaceuticals. The agreement covers development in psoriasis and other autoimmune disorders. The deal includes an undisclosed upfront, development milestone, sales milestone and royalties on net sales. ARN-6039 (BOS172767) has completed a Phase I trial, while a Phase II trial is believed to have recently initiated.			
JTE-451	Japan Tobacco	Oral	Phase I	Psoriasis	As of 6 February 2018 it is in a Phase I trial. Previously had JTE-151 in development, which had been terminated as of 2 May 2016.			
Development programme	Phenex Pharma/ Janssen	Oral	Phase I	Autoimmune disorders	Development programme with Janssen worth up to \$135m. In June 2017, Phenex announced the payment of a \$6m milestone payment from Janssen for the initiation of Phase I trial with a RORyt inverse agonist.			
BBI-6000	Orca Pharmaceuticals/ Brickell Biotech	Topical	Preclinical	Psoriasis	Acquired worldwide rights from Orca in November 2015 for a series of topical RORyt inhibitors (undisclosed deal terms). Company expects to complete IND enabling studies in 2018 and to initiate a proof-of-concept clinical trial in psoriasis (topical) by the end of 2018.			
LYC-56056	Lycera	Oral	Preclinical	Autoimmune disorders	LYC-56056 is currently in preclinical development.			
INV-17	Innovimmune Biotherapeutics	Oral	Preclinical	Psoriasis	Most recently presented preclinical psoriasis data (topical treatment) at the 2017 European Academy of Dermatology and Venereology (EADV) annual meeting in Geneva.			
IMU-366	Immunic Therapeutics	Oral	Preclinical	Psoriasis	A Phase I in psoriasis is being planned/in preparation. Out licensed from 4SC in September 2016.			
N/A	Escalier Biosciences	Oral/ Topical	Preclinical	Autoimmune disorders	Completed a \$19m series B financing round in March 2018. It anticipates the topical compound to enter the clinic by mid-2018.			
Development programme	Lead Pharma/Sanofi	Oral	Preclinical	Autoimmune disorders	Signed February 2015. Undisclosed deal value. Plan to be in clinical trials within three to four years of starting the research collaboration. Lead Pharma received an upfront payment and is eligible to receive milestones on research, development, regulatory and commercial progress. Sanofi is responsible for commercial development. Lead Pharma has to date received three undisclosed milestones from Sanofi, most recently in November 2017.			
Development programme	Exelixis/ Bristol- Myers Squibb	Oral	Unknown	Autoimmune disorders	Joint discovery programme. Research period with Bristol-Myers Squibb (BMY) has ended, BMY now has had sole responsibly for its development.			
Development programme	Karo Pharma/ Pfizer	Oral	Unknown	Autoimmune diseases	Signed a deal in December 2011 to develop new treatments for autoimmune diseases based on RORyt. Karo is entitled to milestones of over \$200m plus royalties on sales. In May 2017 it received a \$2m milestone from Pfizer.			

Source: Edison Investment Research



BET BD1: Clinically ready in 2019

Nuevolution's second lead internal programme is focused on the first bromodomain (BD1) of the bromodomain and extra-terminal domain (BET) family of proteins. The company has prioritised atopic dermatitis and/or psoriasis as its lead indication while fibrosis (IPFand Scleroderma) and systemic lupus erythematosus are secondary indications.

Both atopic dermatitis (commonly referred to as atopic eczema) and psoriasis are inflammatory conditions which manifest themselves as dry, scaly skin over the body and in extreme cases cracked raised lesions. Atopic dermatitis is commonly treated with topical corticosteroids and antihistamines. In severe cases, more advanced specific therapies are utilised including targeted biologic therapies like Sanofi's IL-4 antagonist Dupixent (dupiliumab) and Pfizer's PDE-4 inhibitor Eucrisa (crisaborole). Psoriasis treatment often depends on the severity of the disease and co-existence of arthritis. Treatments much like for atopic dermatitis often include topical treatments like corticosteroids in addition to light therapy and general immunosuppressants (eg cyclosporine and methotrexate). Specific biologics like Abbvie's Humira (adalimumab), J&J's Stelara (ustekinumab) and Novartis' Cosentyx (secukinumab) are utilised in the most severe cases. Both are significant indications with consensus forecasts for psoriasis and atopic dermatitis worldwide sales in 2022 of approximately \$20bn and \$6bn respectively (EvaluatePharma). A BET-BD1 inhibitor offers a potentially novel mechanism of action that could attract patients who have failed other classes of therapy.

The most advanced molecules in Nuevolution's BET-BD1 programme are NUE7770 and NUE19796, although additional compounds are still being investigated. In Q218, Nuevolution anticipates nominating the lead candidate to move forward to clinical readiness. In H217, Nuevolution demonstrated in vivo efficacy in multiple inflammatory mouse models. These included a psoriasis/atopic dermatitis model (IL-23 induced ear edema), a collagen-induced arthritis (IL-17) model and a fibrosis model. In a separate in vitro model (Exhibit 4), Nuevolution demonstrated that its compounds could inhibit the chemokine, CCL2 produced from stimulated skin cells (keratinocytes). CCL2 (C-C motif ligand 2) also known as MCP1 (monocyte chemoattractant protein 1) is a cytokine that is known to generate a pro-inflammatory response by recruiting a range of immune components including monocytes, T-cells and dendritic cells.

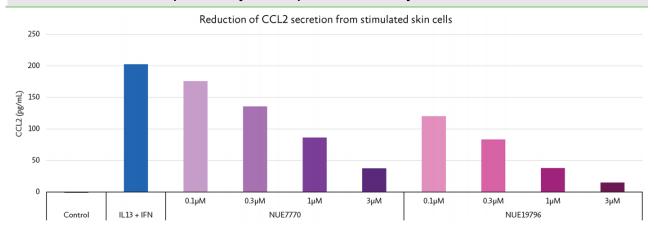


Exhibit 3: Inhibition of CCL2 produced by IL13/IFNy stimulated cells by Nuevolution's BET-BD1 inhibitors

Source: Nuevolution

We note that numerous BET inhibitors are in development (mainly targeting oncology indications). However, the most advanced clinical candidates are generally non-specific in nature and target the majority of BET proteins. Some of the most advanced BET inhibitors are Apabetalone from Resverlogix (<u>Phase III</u>), BMS-986158 (<u>Phase I/II</u>) from Bristol-Myers Squibb, GS-5829 (<u>two ongoing</u>



and one completed Phase I/II trials) from Gilead, INCB057643 (Phase I/II) from Incyte and GSK525762 (Multiple Phase II trials in a <u>range of cancers</u>) from GSK. None of these product candidates are in development for inflammatory conditions, likely as result of their range of toxicities which are not as accepted outside of oncology indications. Nuevolution's selective BET-BD1 inhibitor programme aim to demonstrate a significantly improved clinical profile compared to current BET-BD1 inhibitors due to the selectivity of the inhibition. However, until clinical safety data are available, this is only theorised based on preclinical data.

Rest of the pipeline ready to move out of the shadows

While the RORyt inverse agonist and BET-BD1 programmes continue to lead internal development, the RORyt agonist, Cytokine X and GRP78 programmes in addition to 10 + undisclosed programmes continue to progress through various stages of discovery (Exhibit 1). Every programme in the pipeline is being developed utilising Nuevolution's Chemetics platform.

One of the most advanced is the RORyt agonist programme for use in immune-oncology. While the inverse agonist product candidates aim to dampen an immune response, the agonist product candidates aim to boost an immune response. In the second half of 2017, Nuevolution conducted an in vivo study in a mouse breast tumour model, where it compared the efficacy of a lead internal compound with a competitor with claimed in vivo activity. The study aimed to help develop the understanding of the mechanisms of action at play. Neither Nuevolution's nor the competitor's compounds had an effect. This could indicate either a failure in the model or a failure of the compounds, however, this is expected at this stage of development as multiple models and compounds are tested in order to refine their suitability towards the target disease. Additional RORyt agonists have been identified by Nuevolution and the company aims to further probe the mechanism of action with more tumour models.

Currently the most advanced clinical RORyt agonist product candidate is LYC-55716, in development by Lycera. The company has a <u>Phase I/IIa study</u> in patients with advanced solid tumours, the Phase I component is now complete and patients are currently being enrolled into the Phase IIa with full patient enrolment expected by mid-2018. Most recent efficacy data from the Phase I component of the trial was presented at ESMO 2017, please see our note <u>Defining year as</u> <u>partnerships progress on track</u> for further details. In addition to the aforementioned trial, Lycera has recently initiated a <u>Phase Ib study</u> in patients with metastatic NSCLC in combination with the PD-1 checkpoint inhibitor pembrolizumab (Keytruda). The aim is to enrol 18 patients with data expected in the first half of 2019.

In the Cytokine X programme (exact target undisclosed), progress is advancing as anticipated. In H217, Nuevolution continued lead optimisation of the programme, with the intention of improving compound exposure levels in animals and exploring other chemical series that have not yet been studied. In one mouse inflammation model (Exhibit 5) Nuevolution's compound demonstrated efficacy at the highest concentration on a par with an antibody to the same target. The efficacy of the NUE compound was compared to the antibody, where the antibody is at 100% inhibition. Both were tested mid study and at end study, with the undisclosed disease worsening throughout the study. All compounds were dosed twice daily by a sub-cutaneous injection under the skin.

EDISON

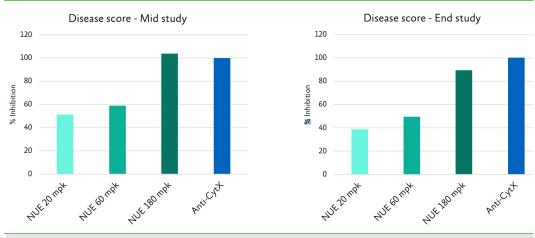


Exhibit 4: In vivo mouse inflammation model, NUE compound vs antibody to same target

Source: Nuevolution

While the exact target is undisclosed, we note inhibition of cytokines by small molecules has never reached commercial approval. Various antibody based inhibitor cytokines do exist, but if Nuevolution can successfully develop a small molecule cytokine inhibitor, it could provide substantial benefits over antibodies, including lower costs, easier administration (oral rather than injection as is the case with antibodies) and better control over side effects due to the typically shorter circulating lifetime of small molecules.

The GRP78 programme is being conducted in collaboration with Cancer Research Technology (CRT) UK and the Institute of Cancer Research (ICR) UK. The programme aims to identify compounds that target GRP78, an intracellular protein that is believed to support cancer cell survival. Compounds that have been selected by Nuevolution are now in the control of CRT/ICR where they are being tested in various cancer cell lines. Further progression of this programme will depend on CRT/ICR.

We note that multiple other undisclosed programmes are in development by Nuevolution and we anticipate these will come to the forefront as the lead assets are either out licensed or clinically developed internally.

Additional near-term partnership expected

Nuevolution's Chemetics technology platform (see <u>Chemetics proof is in the deal making</u> for an in depth description of the Chemetics platform) enables the rapid development of small molecule drugs for 'tough-to-drug' targets. Its DNA-encoded library technology has been methodically developed over the last 17 years (company founded in 2001) to ensure it is effective in finding small molecule drugs to difficult targets. Key to this is its ability to generate small molecule drug libraries that are magnitudes larger than previously possible and management believes that it enables 1,000-fold more compounds to be screened vs traditional high-throughput screening (HTS).

At the end of 2016, Nuevolution signed two significant deals with Amgen (potentially \$410m per target plus royalties) and Almirall (€442m in milestones plus royalties). Both these deals could provide significant long-term revenue streams that would enable Nuevolution to invest in its own internal pipeline. Nuevolution has recently reaffirmed its timelines for another out license or partnership deal, which it expects to occur within three to nine months. We anticipate that an out license is the most likely of these with deal terms on a par with Almirall's. However, we note at this time we have no information to suggest any of these terms are likely.



Amgen, Almirall and Janssen: 2018 is key

The partnerships and collaborations with Almirall, Amgen and Janssen continue as expected. The confidential nature of the collaborations mean little material information has been forthcoming, although we expect this to change in 2018. We predict that Almirall moves the RORyt inhibitor into the clinic in the latter half of 2018 (in dermatology and psoriatic arthritis indications) and Amgen takes up the option on the first product candidate (we forecast before 30 June FY17/18 year end) to emerge from the Nuevolution collaboration. We forecast that both could generate significant revenues in the form of milestone payments. We note that in the near term, two key sensitivities remain in the timing and size of expected milestones from both the initiation of Almirall's Phase I trial and Amgen's research project option.

Nuevolution currently has two programmes (\$410m in research, development and commercial milestones plus royalties for each programme) ongoing in its partnership with Amgen. Of these, one programme was part of the original targets agreed on, while the other was originally part of Nuevolution's own pipeline. Under the terms of the partnership, Nuevolution is responsible for the early research and will collaborate with Amgen on later stages of research. The preclinical development, clinical development and commercialisation of the product are Amgen's responsibility. Nuevolution will receive a licence fee payment if Amgen decides to take up the option to develop a programme through preclinical and clinical research.

In December 2017, a compound from the first cancer programme demonstrated superior efficacy to a competing compound (Exhibit 6). According to the company, the highest dose resulted in near complete elimination of the tumour in this mouse xenograft model.

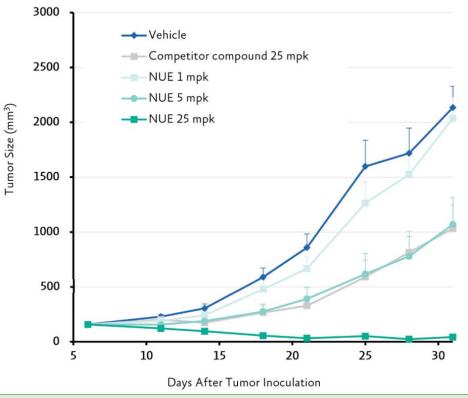


Exhibit 5: Tumour xenograft model - NUE compound tested against competitor

Source: Nuevolution

In the second programme, potential product candidates have been identified and will be tested in a tumour model in Q118.



The RORγt inverse agonist programme (in dermatology and psoriatic arthritis indications) has been transferred to Almirall and we expect the lead molecule to enter Phase I trials in 2018. Nuevolution received €11.2m (SEK109m) gross as an upfront licence payment (before the Spanish withholding tax of SEK20.9m). The deal could provide Nuevolution with up to €172m (SEK1.7bn) in development and regulatory milestones, as well as €270m (SEK2.6bn) in commercial sales milestones and tiered royalties on future net sales. Almirall is a major player in dermatology (€389.8m in worldwide dermatology sales in FY16) and is well-placed to maximise the potential of the RORγt inverse agonist.

The Janssen agreement represents an older-style technology access agreement, which has lower economic value compared to the newer collaborations with Almirall and Amgen. While lower value, it is highly encouraging to see progress and it serves as ongoing validation of the Chemetics technology platform. The original agreement was signed in October 2015 (undisclosed upfront) and to date Nuevolution has thrice publicly announced an expansion of the agreement, receiving payments of \$0.6m in both June 2016 and March 2017, in addition to a recent payment (January 2018) of \$0.75m. This last payment was a result of J&J exercising its option to license one of its research programmes. The disease target is in the area of anti-infectives and Nuevolution are entitled to further research, development and commercialisation milestones, in addition to royalties on net sales.

Sensitivities: Clinical validation is the long term focus

Nuevolution is subject to drug development risks, including clinical development delays or failures. However, Nuevolution's large number (15+) of compounds in parallel development helps to reduce the risk typically associated with pure-play biotech. Additional sensitivities exist around IP protection, regulatory risks, competitor successes, partnering setbacks, and financing and commercial risks. While Nuevolution's strategy minimises the business risk associated with drug development by partnering early on in development, general risk still remains in the partner's willingness to progress these partnerships. One of the key sensitivities for Nuevolution relates to the successful transition of molecules discovered by its Chemetics programme into clinical-stage development; this will enable further validation of its technological capabilities. Financing needs depend on milestone revenues from existing partners and potential new partnering activities; delay or failure to receive future milestones would generate a funding gap during FY19.

Valuation: rNPV of SEK21.0/share or SEK901m (\$109m)

We value Nuevolution at SEK21.0/share (SEK901m) compared with SEK21.4/share (SEK917m) previously. This decrease is predominately due to the negative effects of updating FX rates, a reduction in net cash and a delay to when we anticipate the Almirall Phase I trial to start. We now anticipate that it starts in the next financial year (based on a 30 June year end). We note that in the near term, two key sensitivities remain in the timing and size of expected milestones from both the initiation of Almirall's Phase I trial (forecast for FY18/19) and Amgen taking the option on one of the research projects (forecast for FY17/18).

Our valuation of SEK901m including net cash of SEK110.6m is based exclusively on a risk-adjusted model of the future milestones we expect from the Almirall (SEK9.7 per share), Amgen (SEK8.3 per share) and Janssen (SEK0.4 per share) deals (ie excluding any value of 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 an early stage in preclinical development. Consequently, we see potential upside as further deals are made and/or assets move into clinical development. Specifically for the Amgen deal, our valuation is based



purely on potential development milestones, with no value included from product launches. For Almirall, the majority of the value lies in milestone payments (65%), given the long timeframe to potential launch of the product, with a smaller contribution from royalties on sales (35%).

We note that lead programmes RoRyt inhibitor (outside of Almirall's selected indications) and BET-BD1 at this stage seem the most likely to be partnered or out licensed. We would anticipate any out licensing deals terms would be similar to that of the 2016 Almirall deal. As such, we believe any potential deal could add approximately SEK9/share to our valuation, an approximate 40% potential upside. However, due to uncertainties on exact indications, markets and clinical status, this number could vary substantially from this estimate.

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)
RORyt inhibitor	Almirall	Psoriasis and PsA	Preclinical	1,188.2	269.6	1,471.2	147.1	416.7	9.7
Various	Amgen	Oncology & neuroscience	Drug discovery	682.1	354.2	0.0	0.0	354.2	8.3
	Janssen	Anti-infective	Drug discovery	43.3	19.3	0.0	0.0	19.3	0.4
Net cash (at 31	Dec 2017)							110.6	2.6
Valuation								909.2	21.2

Exhibit 6: Sum-of-the-parts NPV

Source: Edison Investment Research

Almirall assumptions

We assume \$1.9bn indicative peak sales (2031) in the US and Europe, launch in 2027 in both regions, an 8% royalty rate on sales and a 10% probability of achieving NDA and approval milestones. Our deal milestone estimates are \$9.5m on the start of Phase I in FY18/19; \$17m on start of Phase II in FY19/20; \$42m on start Phase III in FY23/24; \$64m on NDA filing; and \$80m on approval in FY27/28. These anticipated milestones are key to our near-term forecasts and as such any change in the timings or size of these will have a material effect on our valuation.

Amgen assumptions

Given the unknowns in the Amgen deal, in terms of timing, number of targets and specific therapeutic indications, we have made some general assumptions to derive a contribution of SEK8.3 a share to our valuation. We assume three assets move into preclinical development per annum in FY17/18, FY18/19 and FY19/20, precipitating an estimated ~SEK101.5m (\$12.3m) in milestones each year as a result of Amgen exercising its option to take forward the individual assets. We note these assumptions on milestones remain a significant sensitivity to our valuation, any changes in the timing and size of these, or if they are never realised will have a material impact on our valuation. We assume that no products make it to the market, which we believe is realistic considering industry drug approval rates. However, we note that the majority of current value rests in near-term clinical achievements than would arise from any distant potential sales milestones. We assume that one product candidate makes it to a Phase III trial (20% probability), while the other two reach Phase II (30% probability) and Phase I (40% probability) trials. Revenue is inherently difficult to predict but we assume that milestones are activated upon classical development and business achievements (eg initiation of Phase I, II, III trials, NDA submission, launch and sales).

We highlight that this is simply a theoretical scenario and the risk remains that zero programmes are progressed or even launched. Equally, as the Amgen deal is per target, additional candidates (above the three we have assumed) that progress into preclinical development could be a major value driver. Note that we only include milestone payments on our Amgen deal assumptions; we do not ascribe value to royalties on sales at this point as we do not know the potential indications.



Janssen assumptions

We estimate that Nuevolution currently has three Janssen assets in development, which we assume could be worth up to \$30m per asset in milestone payments if they reach the market. However, due to the inherent risks in drug development we assume none of the products in development is approved and that one asset each starts a Phase I trial, a Phase II trial and a Phase III trial. As such, the total milestones per asset are adjusted to reflect the relative progress. We currently do not forecast royalties as the indications are unknown. As such, this could provide further upside to our valuation.

Financials

While Nuevolution has changed its financial year end to 31 December (from 30 June), we retain a 30 June year end in our model and any reference to a financial year (FY) remains this date for now. We will alter our reporting once Nuevolution has reported a full year under the new format. Latest company reported accounts are for the six-month period from 1 July to 31 December 2017; all subsequent text refers to this period unless otherwise stated.

For the aforementioned six-month period, revenues were SEK4.8m, a reduction on the previous period (SEK112.8m) in 2016 which benefited from the SEK109.2m Almirall upfront payment. The SEK4.8m revenues in the period were a result of payments from Janssen.

R&D costs increased slightly on the previous year to SEK52.7m (2016: SEK52.3m) and we anticipate this trend to continue in CY18 as the two lead assets continue to advance through the more expensive latter-stage preclinical research.

SGA increased to SEK16.7m (2016: SEK12.4m) as a result of one-off costs for the impending Nasdaq main market up listing. Net cash of SEK110.6m (gross cash: SEK114.8m) should be sufficient for Nuevolution to operate into FY18/19 without the need for additional revenue. While it is inherently difficult to predict revenues from further deals, we forecast significant near-term revenues from the Amgen and Almirall deals.

Nuevolution received a tax reimbursement of SEK3.6m compared to a tax loss of SEK18.8m in the previous period. The previous large tax loss was a result of Spanish withholding tax on the upfront Almirall payment.

Net loss for the six-month period to 31 December 2017 was SEK61.2m vs a net profit of SEK30.8m in the previous period. This was predominately driven by the Almirall upfront.

Our model suggests that current cash is sufficient to fund operations into FY19, assuming current burn rates and if there were no additional revenues from milestones. After that, financing needs will depend on the exact status of the internal pipeline – progressing one or more candidates into the clinical stage could require additional funding. The cash runway to FY19 is not dependent on our expected milestone payments in the period.

We forecast that revenues should benefit from milestone payments through the ongoing collaborations with Amgen and Almirall and we forecast total revenues of SEK104.9m in FY17/18 (versus SEK120.3m reported in FY16/17) and SEK229.2m in FY18/19. We note changes in the timing and size of milestones paid to Nuevolution will have a material effect on our financial forecasts. We forecast R&D expenditure of SEK113.0m in FY17/18 (SEK107.6m FY16/17) and SEK118.6m in FY18/19.



Accounts: IFRS, Yr end: June, SEK: Thousands	2016A	2017A	2018E	2019E
Income statement				
Total revenues	21,314	120,318	104,858	229,249
Reported gross profit	21,314	120,318	104,858	229,249
SG&A (expenses)	(57,493)	(23,216)	(25,538)	(24,261
R&D costs	(115,707)	(107,587)	(112,966)	(118,615
Adjusted EBIT	(151,886)	(10,485)	(33,646)	86,374
Reported EBIT	(151,886)	(10,485)	(33,646)	86,374
Finance income/ (expense)	(22)	1,045	1,575	1,242
Adjusted PBT	(151,908)	(9,440)	(32,072)	87,616
Reported PBT	(151,908)	(9,440)	(32,072)	87,616
Income tax expense	6,911	(16,046)	11,225	(30,665
Adjusted net income	(144,997)	(25,486)	(20,847)	56,950
Reported net income	(144,997)	(25,486)	(20,847)	56,950
Earnings per share	(,,	(,,	(,)	,
Basic EPS (SEK)	(4.0)	(0.6)	(0.5)	1.3
Diluted EPS (SEK)	(4.0)	(0.6)	(0.5)	1.3
Adjusted basic EPS (SEK)	(4.0)	(0.6)	(0.5)	1.3
Adjusted diluted EPS (SEK)	(4.0)	(0.6)	(0.5)	1.3
Augusted diluted EFS (SER) Average number of shares - basic (m)	36.5	42.9	42.9	42.9
Average number of shares - date (m)	36.5	43.6	43.6	43.6
	50.5	45.0	45.0	45.0
Balance sheet	E 404	F F20	E 704	E 07
Property, plant and equipment	5,494	5,538	5,761	5,973
Other non-current assets	8,585	6,397	24,752	1,665
Total non-current assets	14,079	11,935	30,513	7,638
Cash and equivalents	205,955	179,595	146,300	225,126
Trade and other receivables	367	93	93	93
Other current assets	14,564	10,032	2,902	2,902
Total current assets	220,886	189,720	149,295	228,121
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	10,986	10,986
Current loans and borrowings	1,222	1,482	1,482	1,482
Other current liabilities	20,044	16,286	15,286	14,286
Total current liabilities	33,428	28,754	27,754	26,754
Equity attributable to company	198,055	169,962	149,115	206,066
Cashflow statement				
Profit before tax	(151,908)	(9,440)	(32,072)	87,616
Depreciation of tangible assets	1,328	1,703	277	288
Share based payments	48,528	(153)	0	(
Other adjustments	22	(1,045)	(1,575)	(1,242
Movements in working capital	19,594	(962)	0	(
Net cash from operating activities (pre-tax)	(82,436)	(9,897)	(33,370)	86,662
Interest paid / received	(224)	(798)	1,575	1,242
Income taxes paid	1,210	(12,520)	0	(7,578
Cash from operations (CFO)	(81,450)	(23,215)	(31,795)	80,325
Capex (includes acquisitions)	(504)	(715)	(500)	(500
Other investing activities	(51)	(9)	0	(000
Cash used in investing activities (CFIA)	(555)	(724)	(500)	(500
Net proceeds from issue of shares	242,061	0	0	(000)
Other financing activities	(1,119)	(1,253)	(1,000)	(1,000
Cash from financing activities (CFF)	240,942	(1,253)	(1,000)	(1,000
Increase/(decrease) in cash and equivalents	158,937	(25,192)	(33,295)	78,825
Cash and equivalents at beginning of period	46,250	205,955	179,595	146,300
Cash and equivalents at end of period	205,955	179,595	146,300	225,126
	205,955	119,090	140,300	220,120



Contact details

Nuevolution Ronnegade 8 2100 Copenhagen Denmark +45 7020 0987 www.nuevolution.com

Management team

Chief Executive Officer: Alex Haahr Gouliaev

Alex Haahr Gouliaev holds an MSc and PhD in chemistry from Aarhus University, Denmark. He is a co-founder of Nuevolution and has served as executive vice president, chemistry and drug discovery from 2001 until he was appointed CEO in September 2005. Prior to co-founding Nuevolution, he was director of medicinal chemistry, member of the management group, and a member of the board of directors at NeuroSearch A/S, where he worked for six years.

Chief Scientific Officer: Thomas Franch

Thomas Franch holds an MSc and PhD in molecular biology from Odense University. Thomas joined Nuevolution in 2001, and has been a key scientist for the development and patent protection of the Chemetics technology. From 2006, he served both as chief technology officer and director of biology, leading the company's biology function and technological efforts including process optimisation. Thomas was appointed chief scientific officer in 2012. Prior to joining Nuevolution, Thomas was the CEO of RNA Tech Aps.

Revenue by geography

N/A

Chief Financial Officer: Henrik Damkjaer Simonsen

Henrik Simonsen joined Nuevolution in August 2015. He has extensive experience as an analyst of pharmaceutical and biotech companies. His most recent position was at SEB, where he was director, responsible for life science, in SEB Corporate Finance. Prior to that, he was senior analyst at SEB Equities (2004-11). From 1990-2004, he was an equity analyst and senior equity analyst at Nordea Securities.

Chief Business Officer: Ton Berkien

Ton Berkien joined the company in 2014. His most recent position was at Takeda/Nycomed, where he was acting head of corporate development/M&A, responsible for several M&A transactions. Prior to Takeda, he held a similar position at Nycomed Pharmaceuticals. During 2003-07, Ton was director of competitive intelligence at Ferring Pharmaceuticals.

Principal shareholders	(%)
SEB Venture Capital	23.5
Sunstone Capital	20.8
Industrifonden	20.0
SEB Utvecklingsstiftelse	7.7
LMK Forward	2.7
SEB Pensionsstifelse	2.7
Avanza Pensionförsäkrings AB	2.5

Companies named in this report

Allergan (AGN), Almirall (ALM), Amgen (AMGN), AstraZeneca (AZN), Celgene (CELG), Gilead (GILD), GlaxoSmithKline (GSK), Incyte (INCY), Janseen, Lycera, Novartis (NOVN).

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