EDISON

Nicox

Mid-year update

Continuing to move towards data inflection points

Pharma & biotech

Nicox provided a mid-year business update on 16 July and reported details on the progress of its key programmes. The company's lead internal programmes, NCX-470 and NCX-4251, continue to advance in their respective clinical trials. Top-line data from Mont Blanc, the first of two Phase III NCX-470 studies in glaucoma and ocular hypertension, is expected in Q222. Data from the second Phase III trial, Denali, are now expected in 2023 (versus Q422 previously), and we have revised our potential US launch timing estimate to H224 (vs H124 previously). Nicox recently completed final dosing and follow-up in the NCX-4251 Mississippi Phase IIb in acute blepharitis, an indication with no specific FDA-approved product to date. Top-line Mississippi data are expected in September 2021.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/19	8.3	(16.0)	(0.40)	0.0	N/A	N/A
12/20	14.4	(10.2)	(0.30)	0.0	N/A	N/A
12/21e	8.8	(17.2)	(0.46)	0.0	N/A	N/A
12/22e	11.9	(16.1)	(0.43)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments. Normalised 2020 figures differ from reported amounts due primarily to the €6.9m loss reported following the divestment of Nicox's holdings in VISUfarma.

NCX-470 promises best-in-class IOP lowering efficacy

We believe that NCX-470, if approved, could become the most potent single-agent glaucoma drug on the market in terms of intraocular pressure (IOP) lowering efficacy. NCX-470 (0.065%) has shown statistical superiority in IOP lowering to prostaglandin F2α (PGA) drug latanoprost in Phase II, delivering up to 1.4mmHg further IOP reduction at day 28. The higher NCX-470 concentration (0.1%) used in the Phase III programme may allow for even higher incremental IOP reduction to latanoprost. If efficacy is met in these trials, NCX-470 could potentially become the first non-combination glaucoma drug product in pivotal studies with statistical superiority to a standalone PGA drug, which we believe should support its market adoption and competitiveness.

Partnered commercial products continue to grow

Nicox reported that the number of US prescriptions for Vyzulta rose by 21% y-o-y in Q221 and that for Zerviate it increased by 712% y-o-y, with q-o-q growth shown in each quarter since Zerviate's Q120 launch. While prescriptions growth has been robust, total net royalties were flat y-o-y and q-o-q in Q221, at €0.6m. The lower than anticipated sales growth was due to pricing considerations in reimbursement.

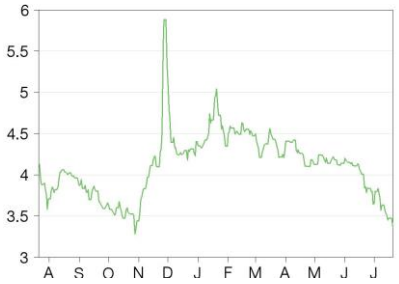
Valuation: rNPV of €325m

Nicox reported H121 gross cash and equivalents of €36.5m, which we believe should fund its operations into H222. We have rolled forward our estimates and, as stated above, pushed back our NCX-470 launch timeline to H224. We now obtain a risked net present value (rNPV) of €325m, up from €322.4m previously. After adding €18.5m in net H121 cash, we obtain an equity value of €343.5m, or €9.26 per share.

21 July 2021

Price	**€3.37**
Market cap	**€125m**
	$1.18/€
Net cash (€m) at 30 June 2021	18.5
Shares in issue	37.1m
Free float	98%
Code	COX
Primary exchange	Euronext
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(15.9)	(18.8)	(16.2)
Rel to TA-100	(13.0)	(20.6)	(32.4)
52-week high/low		€5.88	€3.28

Business description

Based in France, Nicox develops therapeutics for the treatment of ocular conditions. Lead development candidate NCX-470 is in Phase III studies for the treatment of glaucoma. Nicox also receives licence revenue from its partners for its FDA-approved drugs Vyzulta and Zerviate.

Next events

Phase IIb NCX-4251 top-line results	Q321
Mont Blanc Phase III NCX-470 top-line results	Q222

Analysts

Pooya Hemami, CFA +1 646 653 7026

Maxim Jacobs, CFA +1 646 653 7027

healthcare@edisongroup.com

Edison profile page

Nicox is a research client of Edison Investment Research Limited

Mid-year pipeline update

Nicox provided a mid-year business update on 16 July and reported details on the progress of its key programmes. Overall progress was generally consistent with our prior expectations as the company's lead internal programmes, NCX-470 and NCX-4251, continue to advance in their respective clinical trials.

NCX-470 is based on the company's proprietary nitric oxide (NO) donating platform, which combines an NO-donating molecule with an analogue of established prostaglandin F2α (PGA) drug bimatoprost, thereby providing an additional mechanism for the drug to reduce IOP. Top-line data from Mont Blanc, the first of two Phase III studies, continues to be guided for Q222. More than 443 out of the 670 patients planned to be included in the Mont Blanc study have been randomized into the study, and 318 patients have completed the three-month efficacy evaluation. Results from the second Phase III study, Denali, previously guided for Q422, have been pushed back to 2023. We have pushed back our forecast NCX-470 launch timeline from H124 to H224.

The primary endpoint of both studies is the mean IOP reduction from a time-matched baseline at 8am and 4pm time points at weeks two and six and month three visits. IOP reduction is the most widely accepted measure of a glaucoma treatment's efficacy in decelerating disease progression. As discussed in our initiation report, PGA drugs are the most commonly used first-line glaucoma treatment, and bimatoprost (marketed as Lumigan 0.01% by AbbVie) is currently the best-selling branded glaucoma drug in the United States in terms of revenue. In Nicox's Phase II study (Dolomites), NCX-470 (at 0.065% concentration) demonstrated both statistical non-inferiority and superiority in IOP lowering than PGA drug latanoprost at day 28, being up to 1.4mmHg superior (in IOP lowering efficacy) to it at day 28 ($p<0.025$). The chosen NCX-470 concentration (0.1%) in Mont Blanc and Denali is higher than the 0.065% used in the Dolomites study and hence it is possible that these trials could show a higher incremental IOP reduction to latanoprost. If such efficacy is confirmed in these trials, NCX-470 could potentially become the first non-combination glaucoma drug product in pivotal studies with statistical superiority to a standalone PGA drug, which we believe should support its market adoption and competitiveness.

NCX-4251 is a proprietary ophthalmic suspension of fluticasone propionate nanocrystals being developed for acute exacerbations of blepharitis. On 2 July, Nicox announced that the last patient in the NCX-4251 Mississippi Phase IIb study had completed the two-week treatment phase as well as the required two-week follow-up period. The study enrolled over 200 patients and top-line results are expected in September 2021. If the results are positive, an end-of-Phase II meeting with the FDA is planned for early 2022, which will help inform the next development steps.

Partnered products see prescription increases

Nicox obtains recurring revenue from two out-licensed, commercial-stage assets, Vyzulta (latanoprostene bunod) and Zerviate (topical cetirizine). Vyzulta, the first NO-donating PGA drug approved for the treatment of glaucoma, is commercialised by Bausch + Lomb (B+L), Nicox's exclusive commercial partner for the product, entitling Nicox to net royalties of c 6–12% of global sales. Nicox reported that the number of US prescriptions for Vyzulta rose by 21% y-o-y in Q221 (compared to an 18% y-o-y increase in Q121 as reported by B+L). In addition to the US, B+L is also commercializing Vyzulta in Canada, Argentina, Mexico, Hong Kong and Taiwan, and the drug is also approved in Brazil, Colombia, Qatar, South Korea, United Arab Emirates and Ukraine.

Zerviate is an antihistamine drug approved by the FDA for the treatment of ocular itching associated with allergic conjunctivitis. Zerviate is licensed by Nicox in the United States to Eyevance (acquired by Santen in September 2020) and was launched in the United States in Q120. Nicox's effective royalty from Eyevance is c 5% until certain manufacturing costs under their licensing agreement are covered, after which the royalty rate rises to 8–15%. Nicox reported that the total number of US

Zerviate prescriptions increased by 712% y-o-y in Q221 (which we estimate corresponds to c 11,300 in Q221), showing a healthy increase from the period following the launch, although Santen/Eyevance sales have not been disclosed yet. Nicox also licensed Zerviate to Ocumension in the Chinese market, to Samil in South Korea, and in Q221 the company out-licensed it to Laboratorios Grin (a wholly owned subsidiary of Lupin), for Mexico. Zerviate has not yet been commercialised in these regions yet.

While prescriptions for both Vyzulta and Zerviate have risen y-o-y, net royalties (consisting of total royalty payments received by Nicox after its own royalty payment obligations[1] to Pfizer are paid) were flat y-o-y and q-o-q in Q221, at €0.6m. Nicox indicates that for Vyzulta, the Q221 revenue growth trend was lower than anticipated due to pricing considerations in reimbursement. This could be due to a decrease in the net selling price per bottle as new insurer(s) negotiated lower reimbursement prices, or re-negotiations of existing coverage plans resulting in pricing adjustments, or that the 'coverage mix' of prescriptions reflected a lower net pricing mix (from all the plans covering Vyzulta), or a combination of these factors. Altogether, as Vyzulta's market presence matures (the product was launched in the United States in late 2017), these factors or fluctuations should diminish and there should be less fluctuation in the net realized average price, so we would anticipate that net sales growth should match net prescriptions growth more closely going forward.

Financials

Nicox reported that at 30 June 2021 it had €36.5m in cash and equivalents versus €42.0m at 31 March 2021. It also reported €18.0m in gross H121 debt consisting of €16.0m in the form of a bond financing agreement with Kreos Capital and a €2m credit agreement with Société Générale and LCL, guaranteed by the French State and granted in August 2020. Nicox expects the cash at mid-2021 to be sufficient for it to meet its current requirements for the next 12 months. This is consistent with our maintained estimate that Nicox has sufficient funds on hand to operate into H222.

Nicox also reported in July that it will receive $2m from Ocumension after amending its March 2019 agreement with Ocumension covering the latter's exclusive rights to develop and commercialise Zerviate in the Chinese and majority of South-East Asian markets. Nicox received $2m as a full advance payment of the future development and regulatory milestones for the product, but will remain eligible to receive the same sales milestones of up to $17.2m, together with tiered royalties of between 5% and 9% of net Zerviate sales by Ocumension. Zerviate is currently being assessed in a confirmatory Phase III trial in China by Ocumension, to support a Chinese new drug application for the treatment of ocular itching associated with allergic conjunctivitis. We view this revision of their agreement as a positive as it confirms the value that Ocumension sees in Zerviate for the Chinese market, and also helps provide non-dilutive capital to Nicox.

While we have revised our working capital and stock-based compensation forecasts and revised deferred revenue timing assumptions relating to the company's agreement with Ocumension, we have not adjusted our near- to medium-term operating expense forecasts. We may review our assumptions once the company reports full H121 financial results in September. We have pushed back our estimate for the potential launch of NCX-470 from H124 to H224, to account for the new timeline for Denali clinical data.

We continue to model a €10m fund-raise in 2022, followed by an additional €10m in 2023 and €20m in 2024 (all fund-raisings modelled as illustrative debt). Following the anticipated NCX-470 launch in H224, we do not expect Nicox to require additional capital as its royalty streams plus NCX-470 sales should enable it to start achieving consistent positive operating income starting in FY25.

[1] Nicox recovered rights to latanoprostene bunod from Pfizer in 2009 and it must pay royalties to Pfizer proportionate to the product's net sales. After giving effect to these payments, the net royalty that Nicox receives on net Vyzulta sales is between 6% and 12% of net product sales. We model the payments to Pfizer as part of Nicox's cost of sales.

Valuation

We have rolled forward our estimates and, as stated above, pushed back our NCX-470 launch timeline to H224. We have also adjusted our US$/€ forex assumption to 1.18, from 1.19 previously. Following these changes, we now obtain an rNPV of €325m, up from €322.4m previously. After adding €18.5m in net H121 cash, we obtain an equity value of €343.5m, or €9.26 per share.

Exhibit 1: Nicox rNPV assumptions

Product contribution	Indication	Stage	NPV (€m)	Probability of success	rNPV (€m)	rNPV/ share (€)	Launch year	Peak sales (€m) in 2030
NCX-470 (net of R&D and SG&A costs) in US market	Glaucoma	Phase III ongoing	393.7	50%	189.7	5.11	2024	310
NCX-470 (net of R&D and SG&A costs) in Europe and unpartnered regions	Glaucoma	Phase III	190.9	35%	62.0	1.67	2026	157
NCX-470 licence fees from Ocumension (China and other)	Glaucoma	Phase III ongoing	9.3	50%	4.4	0.12	2024	2.7*
NCX-4251 (net of R&D and SG&A costs) sales and licence fees/royalties	Acute blepharitis	Phase IIb ongoing	58.8	40%	20.7	0.56	2025	52.0
Vyzulta royalties from Bausch + Lomb	Glaucoma	Commercial	93.5	100%	93.5	2.52	2017	18.2*
Zerviate royalties from Eyevance and others	Allergic conjunctivitis	Commercial	20.3	100%	20.3	0.55	2020	4.9*
Corporate costs			(65.7)	100%	(65.7)	(1.77)		
Total			700.7		325.0	8.76		
Net cash (H121) excluding lease liabilities			18.5		18.5	0.50		
Total equity value			719.2		343.5	9.26		
FD shares outstanding (000s) (30 June 2021)			37,113					

Source: Edison Investment Research. Note: *Reflects net licence income and royalties received by Nicox and not commercial sales by licensee.

Exhibit 2: Financial summary

€'000s	2018	2019	2020	2021e	2022e	2023e	2024e
31-December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS							
Revenue	4,717	8,260	14,423	8,822	11,886	17,345	23,047
Cost of Sales	(690)	(1,405)	(1,516)	(1,578)	(2,387)	(4,817)	(5,880)
Gross Profit	4,027	6,855	12,907	7,244	9,499	12,528	17,168
General & Administrative	(9,506)	(7,666)	(6,677)	(6,837)	(7,097)	(10,432)	(23,026)
Net Research & Development	(15,491)	(16,883)	(11,991)	(16,700)	(17,350)	(12,350)	(7,350)
Amortisation of intangible assets	0	(659)	(1,252)	(1,162)	(1,141)	(1,121)	(1,101)
Operating profit before exceptionals	(20,970)	(18,353)	(7,013)	(17,454)	(16,089)	(11,374)	(14,309)
EBITDA	(20,718)	(17,230)	(5,270)	(15,939)	(14,597)	(9,916)	(12,838)
Depreciation & other	(252)	(464)	(491)	(354)	(350)	(338)	(370)
Operating Profit (before amort. and except.)	(20,970)	(17,694)	(5,761)	(16,292)	(14,948)	(10,254)	(13,208)
Exceptionals including asset impairment	302	(6,115)	(6,621)	0	0	0	0
Other	0	0	0	0	0	0	0
Operating Profit	(20,668)	(23,809)	(12,382)	(16,292)	(14,948)	(10,254)	(13,208)
Net Interest	2,390	1,690	(4,436)	(901)	(1,171)	(2,153)	(3,073)
Profit Before Tax (norm)	(18,580)	(16,004)	(10,197)	(17,193)	(16,118)	(12,406)	(16,281)
Profit Before Tax (FRS 3)	(18,278)	(22,778)	(18,070)	(18,355)	(17,259)	(13,527)	(17,381)
Tax	(113)	3,856	(28)	0	0	0	0
Profit After Tax and minority interests (norm)	(18,693)	(12,148)	(10,225)	(17,193)	(16,118)	(12,406)	(16,281)
Profit After Tax and minority interests (FRS 3)	(18,391)	(18,922)	(18,098)	(18,355)	(17,259)	(13,527)	(17,381)
Average Number of Shares Outstanding (m)	29.6	30.3	33.7	37.2	37.3	37.5	37.6
EPS - normalised (€)	(0.63)	(0.40)	(0.30)	(0.46)	(0.43)	(0.33)	(0.43)
EPS - normalised and fully diluted (€)	(0.63)	(0.40)	(0.30)	(0.46)	(0.43)	(0.33)	(0.43)
EPS - (IFRS) (€)	(0.62)	(0.62)	(0.54)	(0.49)	(0.46)	(0.36)	(0.46)
Dividend per share (€)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET							
Fixed Assets	112,498	110,660	89,745	88,586	87,421	86,395	85,501
Intangible Assets	71,397	72,120	64,848	63,686	62,545	61,424	60,323
Tangible Assets	25,628	27,517	24,829	24,832	24,808	24,903	25,109
Investments in long-term financial assets	15,473	11,023	68	68	68	68	68
Current Assets	26,092	32,146	52,521	36,048	26,005	26,738	28,121
Short-term investments	0	0	0	0	0	0	0
Cash	22,059	28,102	47,195	28,988	18,499	16,136	16,902
Other	4,033	4,044	5,326	7,060	7,506	10,602	11,218
Current Liabilities	(8,069)	(9,828)	(15,405)	(15,468)	(12,546)	(15,094)	(12,263)
Creditors	(8,069)	(7,751)	(10,116)	(10,179)	(7,257)	(9,805)	(6,974)
Short term borrowings	0	(2,077)	(5,289)	(5,289)	(5,289)	(5,289)	(5,289)
Long Term Liabilities	(16,868)	(23,681)	(26,051)	(26,051)	(34,351)	(44,351)	(64,351)
Long term borrowings	0	(9,045)	(12,687)	(12,687)	(22,687)	(32,687)	(52,687)
Other long-term liabilities	(16,868)	(14,636)	(13,364)	(13,364)	(11,664)	(11,664)	(11,664)
Net Assets	113,653	109,297	100,810	83,115	66,529	53,688	37,007
CASH FLOW							
Operating Cash Flow	(21,533)	(17,741)	(956)	(16,949)	(18,992)	(9,777)	(15,585)
Net interest and financing income (expense)	2,390	1,690	(4,436)	(901)	(1,171)	(2,153)	(3,073)
Tax	0	0	0	0	0	0	0
Capex	(268)	(95)	(20)	(357)	(326)	(434)	(576)
Acquisitions/disposals	0	0	0	0	0	0	0
Financing	0	11,290	13,321	0	0	0	0
Dividends	0	0	0	0	0	0	0
Net Cash Flow	(19,411)	(4,856)	7,909	(18,207)	(20,489)	(12,363)	(19,234)
Opening net debt/(cash)	0	(37,532)	(28,003)	(29,287)	(11,080)	9,409	21,772
HP finance leases initiated	0	0	0	0	0	0	0
Other	56,943	(4,673)	(6,625)	0	0	(0)	0
Closing net debt/(cash)	(37,532)	(28,003)	(29,287)	(11,080)	9,409	21,772	41,006
Lease debt	N/A	1,527	1,099	1,099	1,099	1,099	1,099
Closing net debt/(cash) inclusive of IFRS 16 lease debt	(37,532)	(26,476)	(28,188)	(9,981)	10,508	22,871	42,105

Source: Company reports, Edison Investment Research

General disclaimer and copyright

This report has been commissioned by Nicox and prepared and issued by Edison, in consideration of a fee payable by Nicox. Edison Investment Research standard fees are £49,500 pa for the production and broad dissemination of a detailed note (Outlook) following by regular (typically quarterly) update notes. Fees are paid upfront in cash without recourse. Edison may seek additional fees for the provision of roadshows and related IR services for the client but does not get remunerated for any investment banking services. We never take payment in stock, options or warrants for any of our services.

Accuracy of content: All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report and have not sought for this information to be independently verified. Opinions contained in this report represent those of the research department of Edison at the time of publication. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations.

Exclusion of Liability: To the fullest extent allowed by law, Edison shall not be liable for any direct, indirect or consequential losses, loss of profits, damages, costs or expenses incurred or suffered by you arising out or in connection with the access to, use of or reliance on any information contained on this note.

No personalised advice: The information that we provide should not be construed in any manner whatsoever as, personalised advice. Also, the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The securities described in the report may not be eligible for sale in all jurisdictions or to certain categories of investors.

Investment in securities mentioned: Edison has a restrictive policy relating to personal dealing and conflicts of interest. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report, subject to Edison's policies on personal dealing and conflicts of interest.

Copyright: Copyright 2021 Edison Investment Research Limited (Edison).

Australia

Edison Investment Research Pty Ltd (Edison AU) is the Australian subsidiary of Edison. Edison AU is a Corporate Authorised Representative (1252501) of Crown Wealth Group Pty Ltd who holds an Australian Financial Services Licence (Number: 494274). This research is issued in Australia by Edison AU and any access to it, is intended only for 'wholesale clients' within the meaning of the Corporations Act 2001 of Australia. Any advice given by Edison AU is general advice only and does not take into account your personal circumstances, needs or objectives. You should, before acting on this advice, consider the appropriateness of the advice, having regard to your objectives, financial situation and needs. If our advice relates to the acquisition, or possible acquisition, of a particular financial product you should read any relevant Product Disclosure Statement or like instrument.

New Zealand

The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are 'wholesale clients' for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a 'personalised service' and, to the extent that it contains any financial advice, is intended only as a 'class service' provided by Edison within the meaning of the FAA (i.e. without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision.

United Kingdom

This document is prepared and provided by Edison for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research.

This Communication is being distributed in the United Kingdom and is directed only at (i) persons having professional experience in matters relating to investments, i.e. investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the 'FPO') (ii) high net-worth companies, unincorporated associations or other bodies within the meaning of Article 49 of the FPO and (iii) persons to whom it is otherwise lawful to distribute it. The investment or investment activity to which this document relates is available only to such persons. It is not intended that this document be distributed or passed on, directly or indirectly, to any other class of persons and in any event and under no circumstances should persons of any other description rely on or act upon the contents of this document.

This Communication is being supplied to you solely for your information and may not be reproduced by, further distributed to or published in whole or in part by, any other person.

United States

Edison relies upon the 'publishers' exclusion' from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. This report is a bona fide publication of general and regular circulation offering impersonal investment-related advice, not tailored to a specific investment portfolio or the needs of current and/or prospective subscribers. As such, Edison does not offer or provide personal advice and the research provided is for informational purposes only. No mention of a particular security in this report constitutes a recommendation to buy, sell or hold that or any security, or that any particular security, portfolio of securities, transaction or investment strategy is suitable for any specific person.

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holbom
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia