Novogen

FY17 results update

GDC-0084 Phase II on track to commence Q417

Pharma & biotech

Novogen is on track to commence a Phase II trial of GDC-0084 in glioblastoma in Q4 CY17, in line with previous guidance. It plans to meet with the FDA to discuss trial design as it finalizes preparations for the study. A Phase I trial of Cantrixil in ovarian cancer is well underway, with initial data expected in late 2017 or early 2018 – efficacy data from an expansion cohort at the MTD are likely in H2 CY18. We lift our valuation range slightly to between $69m and $120m ($14.24-24.81 per ADR), while noting that additional funds may be needed in FY18.

Year end	Revenue (US$m)	PTP (US$m)	EPADR ($)	DPADR ($)	P/E (x)	Gross yield (%)
06/16	2.9	(9.2)	(2.25)	0.0	N/A	N/A
06/17	6.8	(8.6)	(1.80)	0.0	N/A	N/A
06/18e	5.9	(13.6)	(2.82)	0.0	N/A	N/A
06/19e	13.9	(8.5)	(1.76)	0.0	N/A	N/A

Note: Converted at A$1/US$0.79 for the table above and throughout the note; Novogen changed the ADR ratio from 25:1 to 100:1 (100 ordinary shares per ADR) on 14 July 2017.

GDC-0084 Phase II to start in Q417

Novogen is on track to initiate a Phase II trial of GDC-0084 (a small molecule inhibitor of the PI3K/Akt/mTOR pathway) in glioblastoma (brain cancer) in Q417. It has appointed Chiltern Oncology to manage the trial, and the manufacture of finished dosage capsules of the drug is almost complete. Consultations with the FDA to discuss key features of the clinical trial design are expected before the study commences. The trial will test GDC-0084 in a subset of glioblastoma patients who are known to obtain little benefit from standard temozolomide chemotherapy; the study is supported by encouraging Phase I data. The clear unmet medical need in this patient group could open access to accelerated approval pathways.

Cantrixil ovarian cancer study progressing

The Phase I trial of Cantrixil in ovarian cancer is recruiting patients at three sites in Australia and two sites in the US. The maximum tolerated dose (MTD) of intra-peritoneal Cantrixil in advanced ovarian cancer is likely to be determined in late 2017 or early 2018. In addition to dosage, safety and tolerability, the study will also assess indicators of efficacy such as radiological responses and biomarkers. After six weeks of single-agent Cantrixil therapy, patients may continue to receive weekly Cantrixil in combination with a chemotherapy agent such as carboplatin. Efficacy data are likely in H2 CY18 from a 12-patient expansion cohort at the MTD.

Valuation: $69-120m in two GDC-0084 scenarios

We lift our indicative valuation range slightly to between $69m and $120m or $14.24-24.81 per ADR (vs $68m to $115m, $14.20-23.70 per ADR), under either post-Phase III approval or accelerated approval scenarios for GDC-0084. The valuation changes reflect rolling forward our DCF model to FY18 and reducing FY18 R&D expenses, offset by a deferral to FY28 of the forecast market launch of the preclinical Trilexium drug as the company focuses on its clinical programs. Novogen had $11.5m cash at 30 June 2017 and we estimate that it may require $6m in additional funding in FY18 and $9m in FY19.

11 September 2017

Price	**$3.05**
Market cap	**$15m**
ADR/Ord conversion ratio 100/1	
Net cash ($m) at 30 June 2017	11.5
ADRs in issue	4.8m
ADR code	NVGN
ADR exchange	NASDAQ
Underlying exchange	ASX
Depository	BNY

ADR share price performance

52-week high/low	$8.68	$2.78

Business description

Novogen is an ASX- and NASDAQ-listed biotechnology company. It is developing GDC-0084 for brain cancer and its super-benzopyran (SBP) drug technology platform. SBPs show activity against cancer stem cells and are active across many different cancers.

Next events

FDA consultation re GDC-0084 Phase II design	H217
Initiate GDC-0084 Phase II	Q417
Initial Cantrixil Phase I data	Q417/Q118

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Exhibit 1: Financial summary

US$000s	2015	2016	2017	2018e	2019e
Year end 30 June	AASB	AASB	AASB	AASB	AASB
PROFIT & LOSS					
Sales, royalties, milestones	0	0	0	0	7,308
Other (includes R&D tax rebate)	1,293	2,896	6,765	5,911	6,589
Revenue	1,293	2,896	6,765	5,911	13,897
R&D expenses	(4,689)	(7,816)	(8,798)	(15,156)	(17,733)
SG&A expenses	(2,582)	(3,431)	(6,001)	(3,420)	(3,482)
Other	0	0	0	0	0
EBITDA	(5,978)	(8,352)	(8,034)	(12,664)	(7,319)
Operating Profit (before GW and except.)	(5,982)	(8,430)	(8,127)	(12,741)	(7,594)
Intangible Amortization	(450)	(1,043)	(52)	(1,006)	(926)
Exceptionals	882	(449)	0	0	0
Operating Profit	(5,550)	(9,923)	(8,179)	(13,747)	(8,520)
Net Interest	(221)	320	(407)	114	10
Profit Before Tax (norm)	(6,653)	(9,153)	(8,586)	(13,633)	(8,510)
Profit Before Tax (reported)	(5,772)	(9,602)	(8,586)	(13,633)	(8,510)
Tax benefit	0	0	157	0	0
Profit After Tax (norm)	(6,653)	(9,153)	(8,430)	(13,633)	(8,510)
Profit After Tax (reported)	(5,772)	(9,602)	(8,430)	(13,633)	(8,510)
Average Number of Shares Outstanding (m)	238.4	427.4	467.8	483.3	483.3
Average Number of ADRs Outstanding (m)	2.38	4.27	4.68	4.83	4.83
EPS - normalized (c)	(2.37)	(2.25)	(1.80)	(2.82)	(1.76)
EPS - diluted	(2.37)	(2.25)	(1.80)	(2.82)	(1.76)
Dividend per share (c)	0.0	0.0	0.0	0.0	0.0
Earnings per ADR - normalized (c)	(236.5)	(224.6)	(180.2)	(282.1)	(176.1)
Earnings per ADR - diluted (c)	(236.5)	(224.6)	(180.2)	(282.1)	(176.1)
Dividend per ADR (c)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	1,178	1,127	12,980	12,963	12,749
Intangible Assets	1,098	650	12,575	11,569	10,644
Tangible Assets	67	467	387	1,376	2,088
Investments	12	10	17	17	17
Current Assets	35,272	26,931	15,389	7,621	8,021
Stocks	0	0	0	0	0
Debtors	119	157	3,367	6,021	6,696
Cash	35,053	26,428	11,419	997	722
Other	100	346	603	603	603
Current Liabilities	(1,404)	(1,131)	(4,253)	(4,253)	(3,140)
Creditors	(1,279)	(1,027)	(1,479)	(1,479)	(365)
Short term borrowings	0	0	0	0	0
Other	(125)	(104)	(2,774)	(2,774)	(2,774)
Long Term Liabilities	0	(121)	(4,099)	(9,629)	(19,109)
Long term borrowings	0	0	0	(5,530)	(15,010)
Other long term liabilities	0	(121)	(4,099)	(4,099)	(4,099)
Net Assets	35,046	26,805	20,017	6,701	(1,478)
CASH FLOW					
Operating Cash Flow	(4,550)	(9,783)	(9,229)	(15,000)	(8,777)
Net Interest	0	320	196	114	10
Tax	0	0	0	0	0
Capex	(77)	(415)	(16)	(1,067)	(988)
Acquisitions/disposals	6	2	(5,607)	0	0
Equity Financing	37,458	618	(14)	0	0
Dividends	0	0	0	0	0
Other	0	0	0	0	0
Net Cash Flow	32,837	(9,258)	(14,670)	(15,952)	(9,754)
Opening net debt/(cash)	162	(35,053)	(26,428)	(11,419)	4,533
HP finance leases initiated	0	0	0	0	0
Other	2,379	632	(339)	0	0
Closing net debt/(cash)	(35,053)	(26,428)	(11,419)	4,533	14,288

Source: Novogen accounts, Edison Investment Research. Note: Solely for the convenience of the reader the financial summary table has been converted at a rate of US$0.79 to A$1. Novogen reports statutory accounts in Australian dollars. These translations should not be considered representations that any such amounts have been or could be converted into US dollars at the assumed conversion rate. Novogen changed the ADR ratio from 25:1 to 100:1 (100 ordinary shares per ADR) effective 14 July 2017.

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