

## 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.

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

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.

#### ADR share price performance



52-week high/low \$8.68 \$2.78

### 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.

#### 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.

### 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.

#### 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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### 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.

**Exhibit 1: Financial summary**

	US\$000s	2015	2016	2017	2018e	2019e
Year end 30 June		AASB	AASB	AASB	AASB	AASB
<b>PROFIT &amp; LOSS</b>						
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
<b>BALANCE SHEET</b>						
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)
<b>CASH FLOW</b>						
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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