

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 finalises 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 A\$87m and A\$152m (A\$0.18-0.31 per share), while noting that additional funds may be needed in FY18.

11 September 2017

Price **A\$0.04**

Market cap **A\$19m**

A\$/US\$0.79

Net cash (A\$m) at 30 June 2017 14.5

Shares in issue 483.3m

Free float 90%

Code NRT

Primary exchange ASX

Secondary exchange NASDAQ

Year end	Revenue (A\$m)	PBT* (A\$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
06/16	3.7	(11.6)	(2.8)	0.0	N/A	N/A
06/17	8.6	(10.9)	(2.3)	0.0	N/A	N/A
06/18e	7.5	(17.3)	(3.6)	0.0	N/A	N/A
06/19e	17.6	(10.8)	(2.2)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding exceptionals and share-based payments.

Share price performance



% 1m 3m 12m

Abs (14.9) (27.3) (61.9)

Rel (local) (14.1) (27.6) (63.6)

52-week high/low A\$0.1 A\$0.0

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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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: A\$87-152m in two GDC-0084 scenarios

We lift our indicative valuation range slightly to between A\$87m and A\$152m or A\$0.18-0.31 per share (vs A\$86m to A\$146m, A\$0.18-0.30 per share), 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 programmes. Novogen had A\$14.5m cash at 30 June 2017 and we estimate that it may require A\$7m in additional funding in FY18 and A\$12m in FY19.

Exhibit 1: Financial summary

	A\$'000s	2015	2016	2017	2018e	2019e
Year end 30 June		AASB	AASB	AASB	AASB	AASB
PROFIT & LOSS						
Sales, royalties, milestones		0	0	0	0	9,250
Other (includes R&D tax rebate)		1,637	3,665	8,563	7,483	8,341
Revenue		1,637	3,665	8,563	7,483	17,591
R&D expenses		(5,935)	(9,894)	(11,136)	(19,184)	(22,447)
SG&A expenses		(3,269)	(4,343)	(7,596)	(4,329)	(4,408)
Other		0	0	0	0	0
EBITDA		(7,567)	(10,572)	(10,169)	(16,030)	(9,264)
Operating Profit (before GW and except.)		(7,572)	(10,671)	(10,287)	(16,128)	(9,613)
Intangible Amortisation		(570)	(1,320)	(66)	(1,273)	(1,172)
Exceptionals		1,116	(569)	0	0	0
Operating Profit		(7,026)	(12,560)	(10,353)	(17,402)	(10,784)
Net Interest		(280)	406	(516)	145	13
Profit Before Tax (norm)		(8,422)	(11,586)	(10,869)	(17,257)	(10,772)
Profit Before Tax (reported)		(7,306)	(12,154)	(10,869)	(17,257)	(10,772)
Tax benefit		0	0	199	0	0
Profit After Tax (norm)		(8,422)	(11,586)	(10,670)	(17,257)	(10,772)
Profit After Tax (reported)		(7,306)	(12,154)	(10,670)	(17,257)	(10,772)
Average Number of Shares Outstanding (m)		238.4	427.4	467.8	483.3	483.3
EPS - normalised (c)		(2.99)	(2.84)	(2.28)	(3.57)	(2.23)
EPS - diluted		(2.99)	(2.84)	(2.28)	(3.57)	(2.23)
Dividend per share (A\$)		0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets		1,491	1,427	16,430	16,408	16,138
Intangible Assets		1,390	822	15,918	14,645	13,473
Tangible Assets		85	592	490	1,742	2,643
Investments		16	13	22	22	22
Current Assets		44,649	34,090	19,480	9,647	10,154
Stocks		0	0	0	0	0
Debtors		151	199	4,263	7,622	8,476
Cash		44,371	33,453	14,455	1,262	914
Other		127	438	763	763	763
Current Liabilities		(1,777)	(1,432)	(5,384)	(5,384)	(3,974)
Creditors		(1,619)	(1,300)	(1,873)	(1,873)	(463)
Short term borrowings		0	0	0	0	0
Other		(159)	(132)	(3,512)	(3,512)	(3,512)
Long Term Liabilities		0	(154)	(5,188)	(12,188)	(24,188)
Long term borrowings		0	0	0	(7,000)	(19,000)
Other long term liabilities		0	(154)	(5,188)	(5,188)	(5,188)
Net Assets		44,362	33,931	25,338	8,483	(1,870)
CASH FLOW						
Operating Cash Flow		(5,759)	(12,383)	(11,683)	(18,987)	(11,110)
Net Interest		0	405	248	145	13
Tax		0	0	0	0	0
Capex		(97)	(525)	(20)	(1,350)	(1,250)
Acquisitions/disposals		8	3	(7,097)	0	0
Equity Financing		47,415	782	(18)	0	0
Dividends		0	0	0	0	0
Other		0	0	0	0	0
Net Cash Flow		41,566	(11,719)	(18,570)	(20,193)	(12,347)
Opening net debt/(cash)		205	(44,371)	(33,453)	(14,455)	5,738
HP finance leases initiated		0	0	0	0	0
Other		3,011	800	(429)	0	0
Closing net debt/(cash)		(44,371)	(33,453)	(14,455)	5,738	18,086

Source: Novogen accounts, Edison Investment Research

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