EDISON

InMed Pharmaceuticals

Financial update

CTA filed on schedule

Pharma & biotech

InMed Pharmaceuticals recently announced that it filed a Clinical Trial Application (CTA) in the Netherlands for INM-755, which is being developed for epidermolysis bullosa (EB). Approval of the CTA is expected around the end of November with the first trial (755-101-HV) expected to begin in December. This trial will test two strengths of INM-755 cream on the intact skin of 22 healthy volunteers. Following the completion of this trial, the company expects to initiate trial 755-102-HV, which would test INM-755 on eight healthy volunteers with small wounds.

Year end	Revenue (C$m)	PBT* (C$m)	EPS* (C$)	DPS (C$)	P/E (x)	Yield (%)
06/18	0.0	(5.3)	(0.04)	0.00	N/A	N/A
06/19	0.0	(9.1)	(0.05)	0.00	N/A	N/A
06/20e	0.0	(15.6)	(0.09)	0.00	N/A	N/A
06/21e	0.0	(17.3)	(0.10)	0.00	N/A	N/A

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

On the way to human clinical trials

With the submission of its CTA, InMed is on track for initiating the Phase I programme for INM-755 in healthy volunteers by the end of 2019. There will be two separate trials (755-101-HV and 755-102-HV) that will be carried out serially as data from the trial in subjects with normal, intact skin are necessary for the trial in subjects with small wounds. We expect trial 755-101-HV to complete enrolment in Q120 with enrolment for 755-102-HV beginning in H220.

INM-088 development progressing

INM-088 for glaucoma is advancing as the company completed in vitro testing of the compound and initiated multiple formulation and pharmacology studies. These studies are expected to be completed in early 2020. Key IND-enabling studies are expected to begin after these are completed and after discussions with regulators (if needed).

Biosynthesis on track

InMed's *E. coli*-based biosynthesis process continues to move forward. The company is optimising fermentation parameters to maximise yield and continue to work on downstream purification (DSP). The company is on track to complete these activities by year-end. InMed is also investigating an alternative process (the exact nature of which is undisclosed) that may have advantages in terms of cost and yield, and will decide which approach to advance in H120.

Valuation: C$259m or C$1.50 per basic share

We have increased our valuation to C$259m or C$1.50 per basic share (C$1.24 per diluted share), from C$256m or C$1.48 per basic share (C$1.22 per diluted share). The valuation increase is mainly due to increasing the probability of success for INM-755 (from 5% to 7.5%) following product advancement into the clinic. This was partially offset by a lower cash balance. InMed had C$14.8m in cash and marketable securities at 30 September and we believe this provides a runway into FY21.

18 November 2019

Price	**C$0.25**
Market cap	**C$43m**
	C$0.75/US$
Net cash (C$m) at 30 September 2019	14.8
Shares in issue	172.3m
Free float	99.3%
Code	IN
Primary exchange	TSX
Secondary exchange	OTC markets

Share price performance

%	1m	3m	12m
Abs	(2.0)	(10.9)	(55.5)
Rel (local)	(5.2)	(15.8)	(60.3)
52-week high/low	C$0.79	C$0.25	

Business description

InMed Pharmaceuticals is a Canada-based biopharmaceutical company focused on manufacturing and developing cannabinoids. Its biosynthesis platform may be able to produce cannabinoids for less cost and with improved purity compared to currently used methods. The company is also developing a proprietary pipeline, including INM-755 for epidermolysis bullosa, a serious, debilitating orphan indication.

Next events

INM-755 Phase I initiation	Year-end 2019

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Edison profile page

Quarterly update

InMed continues to be on track for initiation of the Phase I programme in healthy volunteers by the end of the year following the submission of a CTA in the Netherlands, where it will conduct the initial clinical trials. The programme will consist of two separate trials (see Exhibit 1). Trial 755-101-HV will enrol 22 healthy volunteers with normal, intact skin and evaluate the systemic and local safety, tolerability and pharmacokinetics (PK) of two dosage strengths of INM-755 cream. Trial 755-102-HV will have around eight healthy volunteers with small wounds to evaluate the local safety of the product. The small blister wounds will be created at the clinical site and will largely mimic the types of wounds typically seen in EB simplex patients. A Phase I/II in approximately 12–15 EB patients is expected to begin in early 2021 following additional IND/CTA filings globally. Note that all these trials will be double blind and vehicle controlled. Importantly, the safety studies can be used as the basis for a clinical trial programme in other indications as INM-755 may have applications in other dermatologic indications involving inflammation, pain and itch.

Exhibit 1: Expected clinical trial programme

Trial	Type of patients	Expected size	Treatment protocol	Purpose	Timing
Phase I (755-101-HV)	Adult healthy volunteers with normal, intact skin	22	14 days on intact skin; two dosage strengths	Systemic and local safety/PK	Initiate by year-end 2019, complete enrolment by end of Q120.
Phase I (755-102-HV)	Adult healthy volunteers with small wounds	Around 8	Seven days on small wounds; two dosage strengths	Local safety	Initiate after 755-101-HV data are available. Enrolment expected to begin and complete in H220.
Phase I/II	EB patients (first adults, then children)	12–15	30 days on intact skin and possibly wounds; two dosage strengths	Systemic and local safety and efficacy	Initiate in Q121, following IND/CTA filings in additional countries globally.

Source: InMed Pharmaceuticals

The glaucoma programme is advancing. INM-088 has completed in vitro testing and the company has initiated multiple formulation and pharmacology studies. These studies are expected to be completed in early 2020. Key IND-enabling studies are expected to begin after these are completed and after discussions with regulators (if such discussions are necessary). As with INM-755, we believe INM-088 is a ‘minor’ cannabinoid, which will allow InMed to differentiate its clinical programs in the cannabinoid pharmaceutical sector dominated by cannabidiol (CBD) and tetrahydrocannabinol (THC) trials.

Valuation

We have increased our valuation to C$259m or C$1.50 per basic share (C$1.24 per diluted share), from C$256m or C$1.48 per basic share (C$1.22 per diluted share). The valuation increase is mainly due to increasing the probability of success for INM-755 (from 5% to 7.5%) due to product advancement into the clinic. Phase I products typically have a 10% probability of success, so it seems appropriate to increase the probability of success from 5% as the initiation of a Phase I trial is coming very soon. We will raise the probability of success beyond 7.5% as the product advances further. The valuation increase was partially offset by a lower cash balance.

Exhibit 2: InMed valuation

Program	Stage	Probability of success	Launch year	Peak sales (C$m)	rNPV (C$m)
Biosynthesis (manufacturing)	Development	23%	2022	1,574	224
INM-755	Phase I	7.5%	2026	345	20
Total					244.4
Net cash and equivalents (As of 30 September) (C$m)					14.8
Total firm value (C$m)					**259.1**
Total basic shares (as of 30 September 2019, m)					172.3
Value per basic share (C$)					**1.50**
Options and warrants (as of September 2019, m)					37.4
Total diluted shares (as of September 2019, m)					209.7
Value per diluted share (C$)					**1.24**

Source: Edison Investment Research

Financials

InMed reported an operating loss of C$3.3m in its fiscal first quarter (the quarter ending 30 September 2019), up from C$1.5m in the same quarter in the previous year due to the progression of its pipeline. R&D expenses were C$2.3m for the quarter, up from C$0.6m in the same quarter in the previous year. We have lowered our expectations for R&D spending by C$0.3m for both FY20 and FY21 as the run rate was a little lower than we expected. Otherwise our estimates are largely the same.

InMed had C$14.8m in cash and marketable securities at 30 September and we believe this provides a runway into FY21. We continue to forecast the company will raise C$20m over the next two years to fund operations, which we model as illustrative long-term debt.

Exhibit 3: Financial summary

C$000s	2018	2019	2020e	2021e
Year end 30 June	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	0	0	0	0
Cost of Sales	0	0	0	0
Gross Profit	0	0	0	0
Research and development	(1,927)	(5,639)	(10,950)	(11,388)
Selling, general & administrative	(3,367)	(3,798)	(3,862)	(4,017)
EBITDA	(5,530)	(9,685)	(15,159)	(15,751)
Operating Profit (before amort. and except.)	(5,412)	(9,561)	(14,985)	(15,578)
Intangible Amortisation	0	0	0	0
Exceptionals/Other	(3,197)	(4,128)	(2,560)	(2,663)
Operating Profit	(8,609)	(13,689)	(17,546)	(18,240)
Net Interest	88	434	(626)	(1,708)
Other (change in fair value of warrants)	0	0	0	0
Profit Before Tax (norm)	(5,324)	(9,127)	(15,612)	(17,286)
Profit Before Tax (IFRS)	(8,521)	(13,255)	(18,172)	(19,948)
Tax	0	0	0	0
Deferred tax	0	0	0	0
Profit After Tax (norm)	(5,324)	(9,127)	(15,612)	(17,286)
Profit After Tax (IFRS)	(8,521)	(13,255)	(18,172)	(19,948)
Average Number of Shares Outstanding (m)	142.5	171.3	174.9	181.9
EPS - normalised (c)	(3.74)	(5.33)	(8.93)	(9.50)
EPS - IFRS (C$)	(0.06)	(0.08)	(0.10)	(0.11)
Dividend per share (c)	0.0	0.0	0.0	0.0
Gross Margin (%)	N/A	N/A	N/A	N/A
EBITDA Margin (%)	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A
BALANCE SHEET				
Fixed Assets	1,329	1,241	1,807	1,242
Intangible Assets	1,274	1,185	1,160	1,160
Tangible Assets	56	56	647	83
Other	0	0	0	0
Current Assets	26,734	18,548	12,763	5,547
Stocks	0	0	0	0
Debtors	0	0	0	0
Cash	26,477	18,039	12,474	5,258
Other	257	509	288	288
Current Liabilities	(938)	(1,563)	(1,462)	(1,462)
Creditors	(938)	(1,563)	(1,462)	(1,462)
Short term borrowings	0	0	0	0
Long Term Liabilities	0	0	(10,410)	(20,410)
Long term borrowings	0	0	(10,000)	(20,000)
Other long term liabilities	0	0	(410)	(410)
Net Assets	27,125	18,226	2,698	(15,083)
CASH FLOW				
Operating Cash Flow	(4,672)	(8,769)	(15,284)	(17,024)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(56)	(35)	(174)	(192)
Acquisitions/disposals	0	0	0	0
Financing	24,483	273	0	0
Dividends	0	0	0	0
Other	0	0	1	0
Net Cash Flow	19,756	(8,532)	(15,458)	(17,216)
Opening net debt/(cash)	(6,708)	(26,477)	(18,039)	(2,474)
HP finance leases initiated	0	0	0	0
Exchange rate movements	0	0	0	0
Other	14	94	(107)	0
Closing net debt/(cash)	(26,477)	(18,039)	(2,474)	14,742

Source: InMed Pharmaceuticals accounts, Edison Investment Research

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