

RU Pharma

GSM Drug Opportunity Evaluation

Areas of consideration

- Ourselves – who we are and where do we want to go
 - Therapeutic focus, areas of expansion, capabilities, funding (capital markets), competitive dynamics (IP, new technologies)
- Opportunity itself
 - Product viability (technical, clinical, regulatory, IP)
 - Market viability (commercial assessment, pricing, penetration, competition, IP, regulatory/reimbursement)
 - Revenue estimates – pricing, discounting, rebates, chargebacks, gross to net
 - Expense estimates – COGS, R&D, marketing
 - Financing/funding
- Due Diligence – Due Diligence – Due Diligence – Don't Guess

DUE DILIGENCE – DUE DILIGENCE

- Substantiate everything
- Use your resources – internal and external
- Don't guess
- It is all an **EXPERIMENT** based on assumptions
 - Are the assumptions valid?

Central questions

- **Is the risk worth the reward?**
- **Are you pricing the asset accurately?**

RU Pharmaceuticals

- Who Are We?
 - Therapeutic Focus – Autoimmunity/Inflammation
 - \$500 MM Market Cap
 - \$100 MM Cash
 - One Product on the market generating \$50 MM revenue – small in-licensed RA Product
 - Expected cash burn \$25 MM (spending about \$75MM annually)
 - Lead development candidate A entering Phase III this year, with expected approval in 3 years.
 - Will have enough cash to get to profitability in 5 years, but just enough, most likely will need to do a financing in the next three years to support product launch.

GSM Product Opportunity

- Rare Skin Disorder – ICSA (I Can't Study Anymore)
 - Believed to be autoimmune
 - Presents as severe local pain, discolorations of the skin, that wax and wane, *not life-threatening*
 - Current treatments include oral and topical steroids, opioids for pain, heavy make-up if lesions are on the face or hands
 - **NO PRODUCTS CURRENTLY INDICATED FOR ICSA**
 - QOL – patients score ICSA similar to **severe psoriasis**
 - ICSA is *believed* to afflict 5,000 people in the US, EU and ROW
 - Orphan status (US and EU)

GSM Product Opportunity

- Administered SC monthly, *complex biologic*
- Completed Phase II
 - 60 patients
 - 2 to 1 randomization
 - 15 academic centers in US
- Improves the signs and symptoms of ICSEA on a standardized scoring scale
 - 70% improvement with a p of 0.025
 - Visual/cosmetic clearance improvements were marked, P <0.01
 - Pain improvements were clinically meaningful yet variable with p of 0.045

GSM Opportunity

- Ph II Safety Profile
 - Mild skin reactions around injection site, transient
 - Headache, mild and transient in 10% of patients (5% of placebo)
 - Mild and transient LFT elevations in 2 patients
 - Not *believed* to be an issue by thought leaders and SAB

Revenues

- Patient population, US, EU and ROW
 - Is population well defined?
 - Advocacy groups
- Penetration
 - Competitor penetration
 - Advocacy groups
 - Concentration of patients, hospital, primary care

GSM Revenue Model

	2019	2020	2021	2022	2023	2024	2025	2037	2038
USD MM									
US ICSA Patients	1,236	1,249	1,261	1,274	1,287	1,299	1,312	1,479	1,494
Market Penetration	0%	15%	20%	25%	30%	35%	40%	50%	50%
Drug Px	0.20	0.21	0.21	0.22	0.22	0.23	0.23	0.31	0.32
US ICSA Revenue	0	38	53	69	85	103	122	231	239
EU ICSA Patients	1,442	1,457	1,471	1,486	1,501	1,516	1,531	1,725	1,743
Market Penetration	15%	20%	25%	30%	35%	40%	45%	55%	55%
Drug Px	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10
EU ICSA Revenue	22	29	37	45	53	61	69	95	96
ROW ICSA Patients	1,339	1,353	1,366	1,380	1,394	1,408	1,422	1,602	1,618
Market Penetration	3%	8%	13%	18%	23%	28%	33%	33%	33%
Drug Px	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10
ROW ICSA Revenue	3	10	17	24	31	39	46	52	53
Total Revenue	25	78	107	137	169	202	237	378	387

COGS

- In-house, contract manufacturing?
- Royalties
- Complexity, biologic, complex protein, therapeutic protein, small molecule
- Manufacturing patents
- Regulatory issues
- Up front – Cap Ex – build a plant?
- Competitive advantages
 - Are there deficiencies in the market on which we can capitalize?

GSM - COGS

	2019	2020	2021	2022	2023	2024	2025	2037	2038
USD MM									
Total Revenue	25	78	107	137	169	202	237	378	387
COGS	5	16	16	21	25	30	36	57	58
Gross Profit	20	62	91	117	144	172	201	321	329
Gross Margin	80%	80%	85%	85%	85%	85%	85%	85%	85%
R&D	28%	10%	10%	10%	10%	10%	10%	5%	5%
S&M	30%	17%	14%	12%	10%	10%	9%	11%	11%
G&A	10%	10%	8%	5%	5%	5%	5%	5%	5%
OPEX	68%	37%	32%	27%	25%	25%	24%	21%	21%
Operating Margin	12%	43%	53%	58%	60%	60%	61%	64%	64%
Net Income Margin	9%	31%	38%	41%	42%	43%	44%	49%	49%

Sales and Marketing

- Sales People
- Marketing budget (staff and spend)
- Clinical reps
- Build it bottom up, cost per fully loaded rep, etc.
- Also look at comps - check your assumptions

G&A

- Management overhead
- How many managers, CFO, HR, administrative overhead, etc.
- Build it bottom up, cost per individual
- Also look at comps - check your assumptions

GSM – SG&A

	2019	2020	2021	2022	2023	2024	2025	2037	2038
USD MM									
S&M	8	13	14	16	18	19	21	40	42
Number of Reps ICSEA	30	50	53	55	58	61	64	67	67
Rep Salary	0.25	0.3	0.3	0.3	0.3	0.3	0.3	0.6	0.6
G&A	2	8	9	7	8	10	12	19	19
Cash	47	70	111	168	240	327	430	2,326	2,516
Gross Margin	80%	80%	85%	85%	85%	85%	85%	85%	85%
R&D	28%	10%	10%	10%	10%	10%	10%	5%	5%
S&M	30%	17%	14%	12%	10%	10%	9%	11%	11%
G&A	10%	10%	8%	5%	5%	5%	5%	5%	5%
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Net Income Margin	9%	31%	38%	41%	42%	43%	44%	49%	49%

R&D

- Clinical trial requirements for regulatory approval
- Additional indications
- Timing
- Post-marketing commitments
- Investigator sponsored trial (IST) support plans
- Competitive analysis
- Collaborate with marketing, regulatory, clinical, sales and manufacturing
 - Feasibility and buy-in

GSM – R&D

	2019	2020	2021	2022	2023	2024	2025	2037	2038
USD MM									
Total Revenue	25	78	107	137	169	202	237	378	387
R&D	7	8	11	14	17	20	24	19	19
Gross Margin	80%	80%	85%	85%	85%	85%	85%	85%	85%
R&D	28%	10%	10%	10%	10%	10%	10%	5%	5%
S&M	30%	17%	14%	12%	10%	10%	9%	11%	11%
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Income Analysis

- Annual estimate – go out 10, 15, 20 years
- Look at growth rates – check your work – does the growth rate seem reasonable
 - Is it decelerating, why?
 - Is it accelerating, why?
 - Is it lumpy, why?
- Look at margin trends

Taxes

- Are there jurisdictions we can go to lower our tax burden?
 - Ireland, Bermuda, Switzerland
 - Can we invert into another entity
- Does the product come with tax benefits
- All has to be included in model

GSM – Income Analysis

	2019	2020	2021	2022	2023	2024	2025	2037	2038
USD MM									
Total Revenue	25	78	107	137	169	202	237	378	387
Operating Income	3	33	57	80	101	122	144	243	248
Interest	0	0	1	1	2	2	3	21	23
Pretax Income	3	34	58	81	102	125	148	264	271
Taxes	1	10	17	24	31	37	44	79	81
Net Income / Loss	2	24	40	57	72	87	103	185	190
Gross Margin	80%	80%	85%	85%	85%	85%	85%	85%	85%
R&D	28%	10%	10%	10%	10%	10%	10%	5%	5%
S&M	30%	17%	14%	12%	10%	10%	9%	11%	11%
G&A	10%	10%	8%	5%	5%	5%	5%	5%	5%
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Net Income Margin	9%	31%	38%	41%	42%	43%	44%	49%	49%
Y-o-Y Growth %									
Operating Income		1020%	71%	40%	26%	21%	18%	2%	2%
Net Income / Loss		990%	70%	41%	26%	22%	19%	3%	3%

Financing Costs – Cost of Capital

- Cash on hand
- Equity raise
 - Dilution
- Debt
 - Interest expense
- Timing of financing
- Different firms may have different costs of capital, which has implications for your ability to compete

NPV

- What will you use for your discount rate/risk?
 - Is it different for different stages of the project?
- Is there a hurdle rate?
- What should we offer?
- What does it mean for share price?

Discount	PV (MM)
10%	\$ 1,076
12%	\$ 830
14%	\$ 658
16%	\$ 533
18%	\$ 441
20%	\$ 370