COURSE COLOUR CODE: SILVER

INSTITUTE OF MANAGEMENT & INNOVATION

Elective Course

IMI3001H

BIOCOMMERCIALISATION I: ANALYSIS OF TECHNOLOGY DRIVEN INNOVATION

Tim Lee & Duncan Jones

Fall Term, 2022

INSTITUTE OF MANAGEMENT & INNOVATION

UNIVERSITY OF TORONTO MISSISSAUGA

IMI3001H – Biocommercialisation I: Analysis of Technology Driven Innovation

Course Outline (Fall, 2022)

Class Location:	Innovation Complex, Room L1220 (KN-L1220)
Class Times:	Mondays 12-Sep to 5-Dec, 6:30-8:45PM
Instructors:	**Duncan Jones,** MSc, MBA, PMP
	Tim Lee, PhD
Office Hours:	By appointment
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Course Description

In In this course through a series of lectures and case discussions, students learn about the formation, financing, and management of early-stage ventures especially as it relates to the (bio)technology and associated medical device space. Topics include opportunity identification and assessment, preclinical and clinical phases, regulatory procedures and pathways, legal issues including patents and venture finance. Students will each be required to select a young, publicly traded company in which to complete an in-depth analysis, presentation, and report.

IMI3003H, which is offered in the Winter/Spring term, is a complimentary course in which student teams are given the opportunity to learn more about the issues and opportunities facing early-stage (bio)technology ventures through direct experiences working on real projects for select early-stage firms within the community.

Course Objectives

The purpose of this course is three-fold—

1. To expose the students to a wide range of interdisciplinary elements that contribute to the start-up and functioning of a biotech corporation. This includes product conception (proof of concept), as well as the development and commercialisation phases which biotech companies need to consider in bringing their product through the regulatory pathway.
2. To familiarise the students with a series of analytical tools and evaluation frameworks that can be employed to analyse the team, market size, industry attractiveness, competitiveness, product distinction, traction, go-to-market and financing strategies of early-stage firms.
3. To have the students apply this knowledge and these tools in the analysis of the state and potential of individual biotech companies as well as in the synthesis and evaluation of potential strategies.

Reading Materials

No textbook is required for the class. Pre-read materials will be posted on Quercus to introduce the materials and to provide additional context for class discussion as well as assist in completion of the work packages.

Marking Scheme

A. Class participation 15%

1) General contributions 5%
2) Pre-read quizzes 5%
3) Quickwrite exercises 5%

B. Mid-term exam 15%

C. Group report and presentation..... 40%

D. Final exam 30%

TOTAL 100%

Attendance for All Students

All students are required to login before 6:30 PM i.e. at the start of the lecture. Only viewing the recording of a presentation is considered ABSENT unless you have prior approval. You must be virtually present for the event to receive attendance credit. Any effort to forge or misrepresent your attendance will be treated as an academic offence. We understand that absenteeism for work events or "networking" events does occur hence the leniency outlined above. Nevertheless, the MBiotech program has a "brand" to build and protect. In the past we have seen many occasions where students have abused discretionary absence to the point where our guest speakers present to a half empty room. The absenteeism measures here have evolved to protect the obligations of the program to the speakers that we invite and the hard work of the student teams who present.

Class Participation

Students are expected to actively participate in class discussions and to ask questions. Active class involvement augments the learning experience, increases assimilation of material, and stimulates the level of class discussion. Contribution is expected to be relevant to the current discussion and includes asking questions pertinent to the lectures and presentations, clarifying difficult concepts, answering questions, and advancing the discussion to a new issue. Just as important is listening attentively to your classmates and critiquing ideas constructively.

Pre- & Post-Lecture Assignments

Prior to each lecture relevant pre-read articles and short 5-6 question quiz will be posted to Quercus to be completed before class. Following each lecture, the **Quickwrite** responses, where students are given 1 minute or so to write down their thoughts on a topic or response to a question posed in the lecture should be posted to Quercus by 6:00 PM the following Monday, *i.e.* before the next class.

Group Report and Presentation

Each team (2-4 students per team) having decided which early-stage NASDAQ or TSX-trade venture they wish to analyse and seek instructor approval.

The analysis will consist of—

- A 10-minute presentation/pitch to the class including an investment recommendation.
- A report covering the company analysis as well as strategy synthesis and evaluation. The written portion of this report is to be a approximately of 12 pages in length (Margins: all 2·54 cm, 1·5 line spacing, New Times Roman 12 point, additional Figures, Tables, References and Appendices can also be included). The report will be marked by the instructors for completeness, quality and value.

Assignment Due Dates

All assignments (individual report, peer-review report, final individual report, and group report) are due by 6:00PM on the assigned date as outlined in this syllabus. Any updates to the Course Outline will be announced to the class and posted on Quercus. Assignments are to be submitted to Quercus in the specified format (PDF, MS Word, MS PowerPoint). **Late penalties equal to 20% per day** (24-hour period) will apply until the assignment is submitted.

Recording

The lectures will be recorded, and the slide decks will be posted to Quercus to assist in notetaking and study for **personal use only**. The lectures are the intellectual property of the instructor or presenters, and the use of recordings and slide decks must respect this. More specifically, students are not to upload the recordings or slide decks to a shared drive, folder, or hosted platform such as YouTube or Facebook, nor publish an instructor's or peer's notes to a website or sell them.

Re-Marking

Requests for remarking will be entertained. This may result in a higher or a lower grade than that initially given. Requests for remarks are to be provided to the professor within one week of receipt of the grade and each request is to be accompanied by a written explanation (up to one page) from the student outlining why he/she believes the paper is worthy of a higher grade.

Missed Assignments & Tests

In the event a student fails to submit an assignment or misses the final exam due to illness or domestic tragedy, the student must contact the professor and submit a completed University of Toronto official "Student Medical Certificate" (available at: http://www.utm.utoronto.ca/access/medcert.pdf indicating type of illness and date of illness (or other applicable documentation for domestic situations) to the **MBiotech** office within 48 hours of the due/test date, if possible.

Academic Misconduct

Students should note that copying, plagiarising, or other forms of academic misconduct will not be tolerated. Any student caught engaging in such activities will be subject to academic discipline ranging from a mark of zero on the assignment, test or examination

to dismissal from the University. Any student abetting or otherwise assisting in such misconduct may also be subject to academic penalties.

Students agree that by taking this course all required papers may be subject to submission for textual similarity review to https://www.ouriginal.com/ for the detection of plagiarism. The terms that apply to the University's use of this tool are described at https://teaching.utoronto.ca/ed-tech/teaching-technology/pdt/pdt-faq/

IMI Mental Health Resources

IMI graduate students have access to a variety of health and wellness resources which we encourage you to use at any time. The **IMI Embedded Counsellor** is a dedicated counsellor, through the HCC, available to meet with IMI students directly. Call 905-828-5255, share that you are an IMI graduate student, and ask for an appointment. You may also access MySSP (open 24 hours), the Mental Health Wayfinder Tool, Good2Talk and the UTM Health and Counselling Centre at any time.

COURSE SCHEDULE v1.0

NOTE: The dates are fixed, however the order of the presentation of the various topics may change. Notification of all changes will be made on Quercus as early as possible.

#	Date	Who Is Responsible?	Proposed Readings
1	12-Sep	Duncan Jones: Overview of 6 tenets as well as Molecular Templates (MTI/MTEM) overview story with guest, Dr. Leigh Revers	6 tenets model, MTI/MTEM articles
2	19-Sep	Duncan Jones: Basic financials and MTI/MTEM story revisited.	Basic financials, further MTI/MTEM articles
3	26-Sep	Tim Lee: Biopharm processing & commercialisation (bench to manufacturing) Product/device approval by Regulatory body	Process Validation Principals 21 CFR (Code of Federal Regulations) Parts 210 and 211 (Good Manufacturing practices)
4	3-Oct	Tim Lee: Evaluation of Technology – Scientific and commercial considerations	
–	10-Oct	**Thanksgiving/Reading Week: NO CLASS**	
5	17-Oct	Tim Lee: Regulatory approval process for drugs and medical devices	Brief Overview of Risk Analysis
6	24-Oct	Mid-term exam	
–	31-Oct	**Halloween: NO CLASS**	
7	7-Nov	Duncan Jones: Entrepreneurship and patents	No magic, Opportunity identification, To business plan or not,
8	14-Nov	Duncan Jones: Financial modeling/ valuation/ investor needs/partnerships	NPV, Scenario planning, Intro to patents
9	21-Nov	Tim Lee: Markets and competition	
10	28-Nov	Group presentations/Reports due on your select NASDAQ/TSX listed Biotech companies	
11	5-Dec	Final exam	