



TECH 565: Biomedical Business Development for Scientists

(2 credits)

Fall Semester 2019

6011 Executive Boulevard, Suite 325, Rockville, MD 20852

Thursdays 5:30 – 7:30 p.m.

INSTRUCTORS AND CONTACT INFORMATION:

Michael Salgaller, PhD (former biotech entrepreneur and venture capitalist)

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Matthew Miessau (Analyst, Epidarex Capital)

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Virtual Office Hours: By appointment

Preferred Method of Communication: Email

COURSE INFORMATION:

Prerequisites: **Basic or advanced knowledge of science. No business credits required. Registration limited to about 20 students.**

Course Description: This course takes a hands-on approach to biomedical business development. Using the current technology portfolio published on the NIH Office of Technology Transfer web site, students will learn by forming “founder’s teams” to review scientific innovation and commercialization potential to ultimately create a mock company. The course will emphasize technology transfer issues and opportunities related to technology partnerships (from an NIH program perspective). Due diligence will be highlighted. Presentations by entrepreneurs and investors will be highlighted for a “real world” perspective. The course will explore the perspectives of company founders and investors and their contributions to the advancement of science through business creation. For a final grade, students will develop, draft, and present a business plan/pitch at the end of the semester.

Registration: For class registration issues please contact the Foundation for Advanced Education in the Sciences (FAES) at www.faes.org or telephone (301) 496-7976.

Please join FAES LinkedIn group for additional information and events:

http://www.linkedin.com/groups/FAES-Graduate-School-Technology-Transfer-3061323?trk=myg_ugrp_ovr

Course Goal and Major Assignment: Group Project – The Pitch

Students will form groups (of 3-4 depending on total class enrollment) to represent a start-up life science company. The company will simulate the process of licensing a patent (or patent family) from the NIH. Then, they will develop a pitch to present to investors to secure a first round of funding intended to advance the technology towards commercialization. The company may focus on biotechnology, pharma, medical device, diagnostic, or another sector where the technology is applicable. Groups are encouraged to source a technology they find novel and interesting – with a potentially large target market. Final presentations are in the form of a pitch to prospective investors. Teams should assume that the technology is being in-licensed into the company at the current stage of development (which varies based on the patent family and can be discovery, pre-clinical, or in clinical trials), and should tailor the pitch accordingly.

When you complete the course successfully, we are both confident and hopeful that you will be able to:

- Make an investor pitch that should include:
 - A 15-minute PowerPoint presentation outlining the following areas of the company, not necessarily in order. Some guiding questions have also been included in parentheses, however this list is not exhaustive as more areas and questions investors typically ask will be covered during class.
 - Technology you are licensing (What are you developing? What is the mechanism of action/value proposition and how is this unique? What is the current stage of development for the technology?)
 - Market opportunity (What is your target market? How big (patients and dollars) is your target market? What is the unmet need you are addressing and how critical is it for the patient population? What are the customer pain points?)
 - Management team (Who are you? Who are your scientific advisors? Who are you looking for to add to the team?)
 - Use of proceeds for the funds to be raised (What will you do with the money you are raising, how long will this take, and how will performing this work build value? How have you come to determine the budget for the work proposed?)
 - Competitive environment (How is your technology differentiated from others on the market or in development?)
 - Exit (Why should investors expect to make a significant return on their investment in a practical timeframe? Who would acquire/partner with this company? What makes you think so?)

Additional Structure of the Course:

- To help guide the preparation of the pitch deck, a Business Opportunity Form will be sent. This document has several questions intended to guide each group's thinking as the presentation is being drafted. If completed and submitted by the date indicated in the syllabus, the instructors will review the form and flag to each group major red flags or immediate areas of concern. It is not mandatory to complete and submit the Business Opportunity Form. However, it is a useful way to get initial feedback to then integrate into the final presentation. When filling out the form, bullet points/lists are sufficient, as it will not be graded. Instructors are available to answer any additional questions groups have either in class or by email.
- Samples of pitches from previous classes will be provided as well as other sources of real-world examples (see links to sample pitches below).
- Local investors and/or entrepreneurs will act as judges for the pitch presentation, so students should be prepared to answer questions for 5-10 minutes.

Texts:

Recommended Readings:

Biotechnology Entrepreneurship: From Science to Solutions, 1st edition. Salgaller, Michael L., Logos Press, 2010. Example chapter:

Chapter 7 – “Licensing and Technology Transfer”

(Free download at – <http://www.ott.nih.gov/sites/default/files/documents/pdfs/Ferguson-Chapter-7-Biotechnology-Entrepreneurship-From-Science-to-Solutions-2010.pdf>)

The Entrepreneur's Guide to a Biotech Start-up, 4th edition: Kolchinski, Peter.

(Free download at – www.evelexa.com)

New Venture Creation: Entrepreneurship for the 21st Century, 9th edition.

Spinelli, Stephen. McGraw-Hill, 2012.

The Art of Telling Your Story: Tips & Insights for Putting Your Best Foot Forward With Investors and Corporate Partners, King, Rick

(Free download at – <http://www.nist.gov/tpo/sbir/upload/gcr02-831.pdf>)

Supplemental Readings:

Building Biotechnology: Starting, Managing and Understanding Biotechnology Companies, Third Edition, Freidman, Yali, Logos Press, 2008.

Science Business: The Promise, the Reality and the Future of Biotech, Pisano, Gary P., Harvard Business School Press, 2006.

Bad Blood: Secrets and Lies in a Silicon Valley Startup by John Carreyrou – 2019

<https://www.amazon.com/Bad-Blood-Secrets-Silicon-Startup/dp/152473165X>

BIO Staff: “Emerging Therapeutic Company Investments and Deal Trends – 2008-2017”.

(Free download at – [http://go.bio.org/rs/490-EHZ-](http://go.bio.org/rs/490-EHZ-999/images/BIO%20Emerging%20Therapeutics%20Company%20Investment%20and%20Deal%20Trends%20Report%202008-2017.pdf?_ga=2.259740483.873734938.1536002457-607678586.1477514535)

[999/images/BIO%20Emerging%20Therapeutics%20Company%20Investment%20and%20Deal%20Trends%20Report%202008-2017.pdf?_ga=2.259740483.873734938.1536002457-607678586.1477514535](http://go.bio.org/rs/490-EHZ-999/images/BIO%20Emerging%20Therapeutics%20Company%20Investment%20and%20Deal%20Trends%20Report%202008-2017.pdf?_ga=2.259740483.873734938.1536002457-607678586.1477514535)

National Venture Capital Association Yearbook: Thomson Reuters

(Free download at – <http://www.nvca.org/publications>)

Web: Angel Capital Association (<http://www.angelcapitalassociation.org/>)

National Venture Capital Association (<http://www.nvca.org/>)

Biotechnology Industry Organization (BIO) (www.bio.org)

Pharmaceutical Research and Manufacturers of America (<http://www.phrma.org/>)

Advanced Medical Technology Association (<http://www.advamed.org/>)

EY Beyond Borders 2017 Biotechnology report –

[https://www.ey.com/Publication/vwLUAssets/ey-biotechnology-report-2017-beyond-borders-staying-the-course/\\$FILE/ey-biotechnology-report-2017-beyond-borders-staying-the-course.pdf](https://www.ey.com/Publication/vwLUAssets/ey-biotechnology-report-2017-beyond-borders-staying-the-course/$FILE/ey-biotechnology-report-2017-beyond-borders-staying-the-course.pdf)

PWC Moneytree Health Industries reports:

<https://www.pwc.com/us/en/health-industries/publications/healthcare-money-tree.html>)

WSGR Term Sheet Generator

<http://www.wsgr.com/WSGR/Display.aspx?SectionName=practice/termsheet.htm>)

Bio Smart Brief (<http://www.smartbrief.com/bio/>)

Biospace (www.biospace.com)

Newsletters and Blogs for Industry/VC Perspective:

Fierce Biotech (<http://www.fiercebiotech.com/>)

Endpoints News (<https://endpts.com/>)

STAT (<https://www.statnews.com/>)

LifeSciVC (<https://lifescivc.com/>)

BioHealth Innovation (<http://www.biohealthinnovation.org/>) – Local news and job postings, among other services

In the Pipeline (<http://blogs.sciencemag.org/pipeline>)

Both Sides of the Table (<https://bothsidesofthetable.com/>) - Note: more tech focused, but relevant terminologies

Podcasts:

Timmerman Report (<https://timmermanreport.com/>)

Readout LOUD – Stat News (<https://www.statnews.com/category/readout-loud/>)

The Pitch (<https://www.gimletmedia.com/the-pitch>) – Note: more tech focused, but insightful commentary on VC perspectives and how to give a good pitch.

Sample Pitches:

2019 Coulter Investment Forum –

(<http://www.coulterinvestmentforum.com/2019-investment-forum-company-presentations/>)

2016 Coulter Investment Forum –

(<http://www.coulterinvestmentforum.com/2016-investment-forum-company-presentations/>)

Other:

Anchor Ventures speaker series (<http://anchorventures.org/>)

DO NOT HESITATE TO CONTACT ANY OF YOUR INSTRUCTORS IF YOU HAVE ANY QUESTIONS

Important Dates:

- September 27: Drop deadline
- November 15: Audit and withdrawal deadline
- November 25: (Monday) Thanksgiving make-up class
- November 28: Thanksgiving

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Policies:

Academic Policies

- *This course adheres to all FAES policies described in the academic catalog and student handbook, including the Academic Integrity policy listed on page 11 of the academic catalog and student handbook. Be certain that you are knowledgeable about all of the policies listed in this syllabus, in the academic catalog and student handbook, and on the FAES website. As a student in this program, you are bound by those policies.*

Copyright

- *All course materials are the property of FAES and are to be used for the student's individual academic purpose only. Any dissemination, copying, reproducing, modification, displaying, or transmitting of any course material for any other purpose is prohibited, will be considered misconduct, and may be cause for disciplinary action. In addition, encouraging academic dishonesty by distributing information about course materials or assignments which would give an unfair advantage to others may violate the FAES Academic Integrity policy. Course materials may not be exchanged or distributed for commercial purposes, for compensation, or for any purpose other than use by students enrolled in the course. Distributions of course materials may be subject to disciplinary action.*

Guidelines for Disability Accommodations

- *FAES is committed to providing reasonable and appropriate accommodations to students with disabilities. Students with documented disabilities should contact Dr. Mindy Maris, Assistant Dean of Academic Programs.*

Dropping the Course

- *Students are responsible for understanding FAES policies, procedures, and deadlines regarding dropping or withdrawing from the course or switching to audit status.*

Attendance

- *Strongly encouraged.*

Participation

- *Strongly encouraged.*

Late Submission Policy

- *Must request in advance.*

Assignment Formats

- *Power Point*

Citation Format

- *Patent and journal source material should be cited. Marketing and analytical source material should be cited.*

Assignment Submission and Due Dates

- *October 10: Finalize group and submit names to instructors*
- *November 7: Last day to email the Business Opportunity Form for review*
- *December 12: First day of presentations*
- *December 19: Second day of presentations*

Grading Scale:

- *A – a clear investor pitch containing all key elements of an effective presentation, including: description of the market potential and competitive landscape of an NIH technology, technical summary, management team, path to market/commercialization strategy, and IP position.*
- *B – a clear investor pitch containing most key elements of an effective presentation.*
- *C – an investor pitch that shows poor communication skills and does not contain most key elements of an effective presentation.*

WEEKLY SCHEDULE: (Note: Schedule may change due to speaker availability)

WEEK # 1 (September 19, 2019)

Introduction to the course – students, instructors. Course highlights, objectives & background.
(Show example pitch videos)

Introduction to Entrepreneurship – The perspective of the founder in new business development.
Founder's view points and challenges.

Assignment: Start Reviewing NIH technologies & Form “Founders Teams” with Common Interests. NIH Technology Search Link: (<http://www.ott.nih.gov/opportunities>)

(Readings: Salgaller – Chapters 1-3; Kolchinski – Pages 1-10, 19-21;
Spinelli – Pages 3-20, 35-48, 279-334))

WEEK # 2 (September 26, 2019)

Introduction to Entrepreneurship (continued)

(Readings: Salgaller – Chapter 11; Kolchinski – Pages 11-18, 95;
Spinelli – Pages 85-102, 165-210)

WEEK # 3 (October 3, 2019)

Due Diligence – Information resources Biomedical Business Development

WEEK # 4 (October 10, 2019)

Government Partnerships — Cooperative Research Agreements (CRADAs) and other options available at the NIH for biomedical business development. Federal issues, Licensing process, and types of licenses at the NIH. Benefits, pitfalls, and realities of licensing technologies.

(Readings: Salgaller – Chapter 7)

WEEK # 5 (October 17, 2019)

Optional: Investor Pitch Videos

Funding/Financing Part 1 – Perspective of the venture capital industry focused on investments in biomedical based businesses. The viewpoints and challenges of the investors.

(Readings: Salgaller – Chapter 5, 10; Kolchinski – Pages 82-88, 93-94; Spinelli – Pages 395-424, 559-565)

Assignment: Founder's Team Meetings – Students Present Interesting NIH Technologies. Form “Founders Teams” with Common Interests (Group of 3 or 4 required)

Funding/Financing Part 2 – Pros and cons of funding resources – angel investors, incubators, state/federal grants, service providers, corporate partners, etc. Understanding Term Sheets.

(Readings: Salgaller – Chapter 6; Spinelli – Pages 380-391, 444-452)

WEEK # 6 (October 24, 2019)

Funding/Financing Part 2 (Continued) – Pros and cons of funding resources – angel investors, incubators, state/federal grants, service providers, corporate partners, etc. Understanding Term Sheets.

Assignment: Finalize Teams and Submit Team List to Instructors.

(Readings: Salgaller – Chapter 6; Spinelli – Pages 380-391, 444-452)

WEEK # 7 (October 31, 2019)

Funding/Financing Part 3 (Continued) – Perspective of the venture capital industry focused on investments in biomedical based businesses. The viewpoints and challenges of the investors. Understanding term sheets.

Founder’s Team Meetings

WEEK # 8 (November 8, 2019)

Opportunity Assessment - is “good research” a marketable product or service; when does science translate to business; what is your “value proposition”; what’s your market; who are your competitors; who are your customers; and many other things to think about.

(Readings: Salgaller – Chapter 4, 8, 9; Kolchinski – Pages 22-81; Spinelli – Pages 113-151)

Strategic Partnerships – Building a Management Team

(Readings: Kolchinski – Pages 15-18; Spinelli – Pages 247-277)

WEEK # 9 (November 15, 2019)

Elements of a Business Plan or guest speakers

(Readings: Kolchinski – Pages 15-18; Spinelli – Pages 245-276)

Assignment: Submission of a TECH 565 Business Opportunity Outline for Your Company

WEEK #10 (November 22, 2019)

“Bootstrapping” – If VC money is not available, what are alternative financing options for a biomedical start-up? SBIR grants and angel investors.

(Readings: Kolchinski – Pages 89-92; Spinelli – Pages 335-346, 395-397, 455-472)

WEEK #11 (November 25, 2019) – **Place TBD – Thanksgiving replacement class**

Pitching – Do's and Don'ts of Business Plan preparation and the "pitch". What are VCs/investors looking for during a pitch meeting?

(Readings: Art of Telling Your Story – Pages 1-33)

Nuts and Bolts of New Business Formation – You have a team, a plan, and a pitch, what do you do now?

Wrap-up Any Additional Content

===== (November 28, 2019) – Thanksgiving Day No Classes =====

WEEK # 12 (December 5, 2019)

View investor pitch videos – Final Founder's Student Business Plan Team Meetings.

WEEK # 13 (December 12, 2019)

Student Business Plan Team presentations – assess the plans and presentations.

WEEK # 14 (December 19, 2019)

Student Business Plan Team presentations (continued).