University of Colorado Biomedical Proof of Concept Program

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The University of Colorado:

- Three campuses: Boulder, Denver (Anschutz Medical Campus and Downtown Denver) and Colorado Springs
- System level Technology Transfer Office (TTO) provides IP and licensing services to all three campuses
- CU's total enrollment is ~58,000 (~ 12,000 graduate, 80% Colorado resident)
- In FY 2009, CU garnered $711M in research: 60% biomedical related, and over 75% from federal sources

CU Technology Transfer Over the Past Seven Years

Fiscal Year	02-3	03-4	04-5	05-6	06-7	07-8	08-9
Invention disclosures	124	147	177	198	254	235	**258**
U.S. patent apps filed	82	100	139	125	156	193	**206**
Total options/licenses	34	47	59	57	75	58	**61**
Exclusive options/licenses	13	19	22	36	38	44	**50**
License revenue in $MM*	3.1	5.8	21.7	20.6	22.7	6.1	**4.4**
Start-up companies	6	9	9	10	10	11	**11**

*does not include revenue derived from legal settlements which in FY2003-4 amounted to $28.1M, in FY2004-5 $6.7M, in FY 2005-6 $.7M, and in FY2006-07 $1.3M.

The Realities of University IP Creation:

- Most faculty research is "curiosity driven." Investigators optimize their research for publication and to secure further funding (mostly federal) as determined by scientific peer review – not commercial review. Therefore, inventions seldom occur within a context of a well-defined market problem.
- Typically the IP is incomplete, unrefined, and years from market application.
- Faculty do not receive near-term rewards for technology transfer performance, but they understand that to create clinical impact securing IP is essential.
- Small amounts of maturation funding can make a big difference for adopter company acceptance.

Technology Maturation through Proof of Concept Programs:

- Basic Concept – validate the technology proposition by aligning technology drivers with market drivers, thereby accelerating commercialization and increasing prospects for commercial adoption = increase in economic value.
- Maximum impact on the portfolio by focusing on platform or core technologies; maximum impact on the technology by focusing on the key value inflection point(s).
- Inflection point defined by development step(s) necessary to reduce the risk profile for the next participant in the value chain, thereby increasing their propensity to adopt.

Overview of POC Programs:

1. TTO Proof of Concept grant (POCg)

- Funds for technology development of inventions in order to augment patent claims and enhance commercial adoption.
- $10k to $25k direct grant to inventor (zero F&A charge).
- Total TTO POCg biomedical grants since 9/05 = $661,221 awarded for projects ($40,362 returned).

2. State Biotechnology POC grant (POCsbg)

- Funds for development of therapeutic, diagnostic and medical device inventions to advance development and prepare for licensing to Colorado companies (mainly start-ups).
- State provides half the funds, University provides the other half; max $200k/project (8% F&A cost, per State requirement).
- Three years of funding with three additional years budgeted.
- Total first three year biomedical grants = $5,267,703 awarded.

3. TTO Proof of Concept Investment (POCi)

- Funds for technology development to establish/ advance commercial viability for promising start-up biomedical companies that have optioned/licensed CU technology.
- $100K convertible debt investments (loan) per company; loan converts to preferred stock upon qualified investor round of financing (typically VC "A" round).
- Requirements: compelling business plan, business driver (entrepreneur) working in company and with CU inventor, and good prospects for securing additional capital.
- $1,259,987 invested in biomedical companies.

POC Program Processes:

*All POC projects are based on inventions disclosed to TTO.

1. For Proof of Concept grant (POCg)

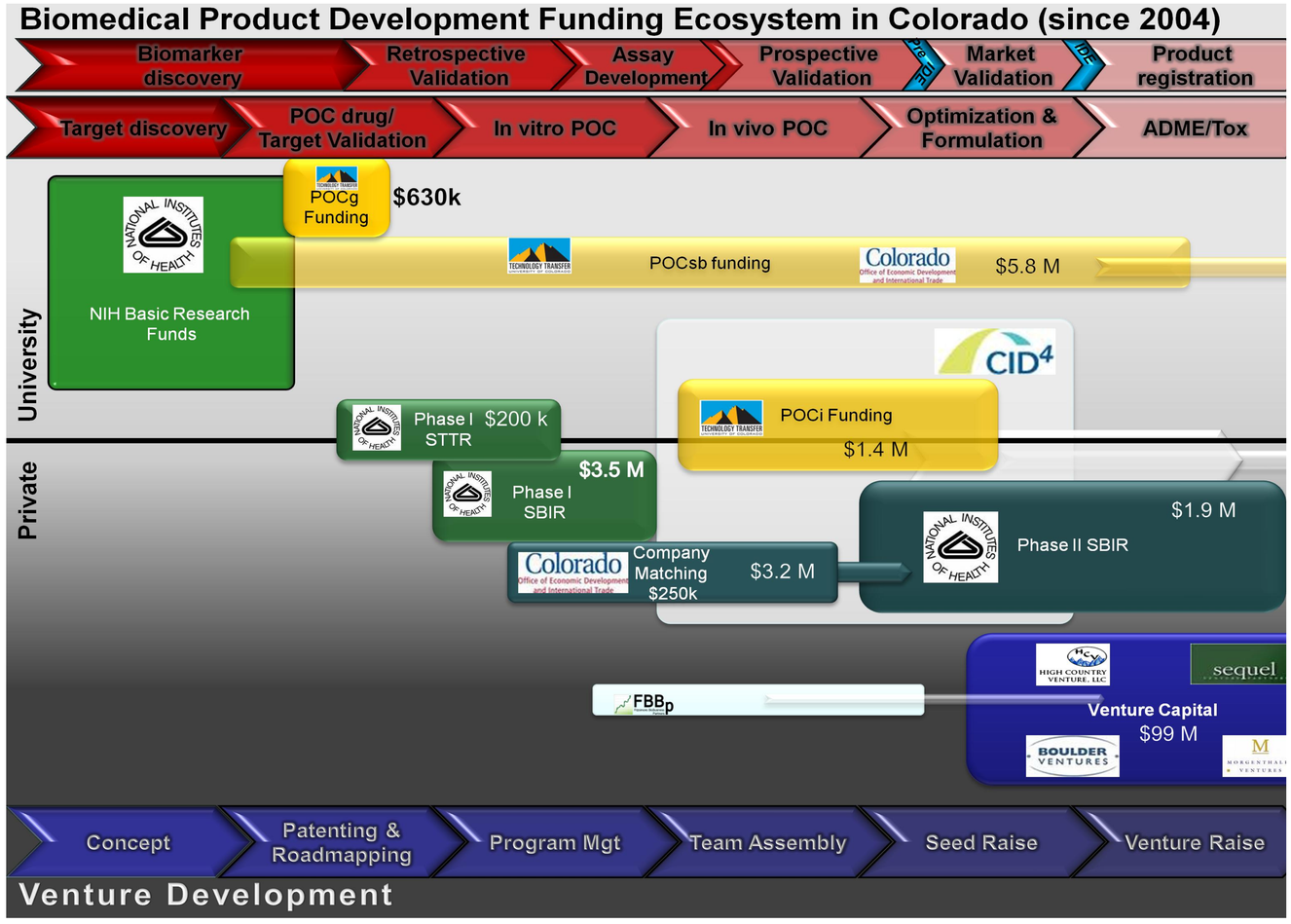
- Initiation during discussion of the opportunity when TTO Licensing Manager (LM) reviews the invention with inventor, preliminary preclinical plan and patent strategy identifies next development steps, scope of work and budget identified, LM makes case to TTO management group for grant, and financial transfer to inventor lab account completed
- Work typically takes 3 to 6 months
- Summary report and in-person presentation to TTO
- Material often transformed into marketing summary and pitch deck

2. For State Biotechnology POC grant (POCsbg)

- Solicitation process begins with broad announcement of grant program, web based proposal instructions and forms and campus level group meetings with interested inventors
- Pre-proposal submitted to identify eligible inventions, in some cases prepare a Provisional Patent Application and work with to create development plan (individually by inventor, with TTO assistance or with the assistance of business advisors)
- Proposals submitted for first cut TTO staff review. Proposals surviving first cut are sent to external review committee (VCs, BD/L, bioentrepreneurs and a few faculty)
- Committee ranks proposals and consensus best proposals selected, consensus weakest rejected and for proposals in the middle presentations by inventors to the external review committee
- Some proposals slightly revised per changes suggested by review committee
- Proposals submitted as a package to State Office of Economic Development for administrative process and adherence to statute review
- State and University enter into grant contract and financial transfer to investigator account
- Work typically takes 12 to 24 months
- Summary report and in-person presentation to TTO
- Material often transformed into marketing summary and pitch deck

3. For TTO Proof of Concept Investment (POCi)

- Discussion of funding opportunity occurs when start-up team is coming together and the business plan is developing
- Typically fall and spring solicitation are announced, web based proposals and forms identified
- Discussion of option to exclusive license underway (sometimes full exclusive license)
- Advisory boards composed of voluntary domain expert advisors help vet the plan and the presentation
- Presentation by business driver and lead inventor to external review committee (VCs, BD/L, serial bioentrepreneurs); often more than one proposal
- Committee provides feedback to TTO and LM works with company to revise proposal.
- Licensing agreement (option or exclusive license) and debt conversion agreement executed
- Company executes work plan, which often includes sponsored research at the University
- Upon predetermined level of qualified financing, debt (with 8% annual interest) converts to preferred stock



Preliminary POC Performance Metrics:

1. Proof of Concept grant (POCg)

- 35 projects, 16 options and licenses executed
- 5 projects deemed non-viable, 14 of the available projects still viable for commercialization

2. State Biotechnology POC grant (POCsbg)

- 34 projects, 6 options and licenses executed
- No projects deemed non-viable, 28 of the available projects still viable for commercialization

3. Proof of Concept Investment (POCi)

- 14 investments and 11 companies still viable
- Of the 3 companies that failed, IP relicensed in 2 cases

Some Lessons Learned:

- Maturation money induces inventions and brings out good technology.
- Early-stage domain/investment expert volunteers conducting evaluations provide objective basis for selection.
- Pre-submission review and advice (building a roadmap) helps ensure a commercial proposition for the project.
- Presentation coaching improves delivery to evaluators.
- Feedback to non-selected applicants improves subsequent application quality.
- TTO support induces others to provide financial support.
- Match funding induces broader financial participation.
- Preliminary evidence strongly suggests that maturation programs enhance licensee adoption and development.

A New Paradigm for Technology Transfer Offices

What the best already do well:

- Identify commercial assets embedded in scientific research results
- Secure patents to protect those assets
- Execute fair and timely license agreements

What are emerging as new core competencies:

- Building relationships with key players in technology entrepreneurial networks and investment value chains
- Make relatively modest Proof of Concept grants and investments to validate technology and align with commercial drivers identified by pre-product roadmaps