
INNOVATION PARTNERSHIPS
UNIVERSITY OF MICHIGAN
Implementation of Socially Responsible Licensing Principles
Bryce Pilz
Assistant Vice President for Research -
Licensing & Strategic Alliances

IT’S OUR JOB TO MAKE SURE THAT EVERY U-M RESEARCH DISCOVERY HAS AN OPPORTUNITY TO CHANGE THE WORLD.

INNOVATION PARTNERSHIPS
UNIVERSITY OF MICHIGAN

MAXIMIZE POSITIVE SOCIETAL IMPACT

AUTM'S NINE POINTS FOR LICENSING IN THE PUBLIC INTEREST

1. Reserve **research rights**
2. **Diligence** milestones to encourage development & use
3. Limit licensing future **improvements**
4. Identify and manage **conflicts of interest**
5. **Broad access** to research tools
6. Carefully consider **enforcement**
7. Be mindful of **export** regulations
8. Be mindful of patent **aggregators**
9. Consider **unmet needs** provisions

Background

- ✓ **Origin:** Principles to ensure licensing in socially responsible manner(adopted 2007)
- ✓ **Adoption:** 120+ institutions signed on, including Fundación Universidad del Norte and Cambiotec AC
- ✓ **Other Models:** Netherlands Federation of University Medical Centers and others have adopted similar principles

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#2 DILIGENCE

Point 2

Exclusive licenses should be structured in a manner that encourages technology development and use



Context

- ✓ **Mission:** Our mission is to enable adoption. Licenses are not permitted to “shelve” technology.
- ✓ **All Licenses:** Diligence milestones are important in ALL licenses (not just exclusive).
- ✓ **Standard Position: :** There must be objective milestones that ensure the technology is brought to market.

DILIGENCE MILESTONES

ARTICLE 5: DILIGENCE MILESTONES

5.1 LICENSEE shall use diligent efforts to develop, secure all applicable government approvals, manufacture, actively market, and fulfill market demand for a full scope of LICENSED PRODUCTS in the TERRITORY, continuously through the term of this Agreement. If the commercialization of multiple LICENSED PRODUCTS is commercially reasonable, then the requirements of this Section shall apply to all such LICENSED PRODUCTS.

5.2 LICENSEE shall achieve the following due diligence milestones for the LICENSED PRODUCTS (together the "MILESTONES") by the stated dates:

(a)

.....

(e)

The requirements of this Section 5.2 are in addition to and do not limit Section 5.1 or any other Section of this Agreement. Each MILESTONE applies only to the first of a series of different LICENSED PRODUCTS, and not with respect to any subsequent LICENSED PRODUCTS. LICENSEE has the right to satisfy its obligations under Section 5.1 and/or Section 5.2 either itself or through the acts of a SUBLICENSEE meeting the obligations of this Agreement.

Common Issues

- ✓ **Milestones:** Can take milestones from licensee's pitch deck. Licensee can suggest dates.
- ✓ **Common Request:** Add a "commercial reasonableness" modifier to the specific milestones.
  - U-M will not agree to this. Need objectivity.
- ✓ **Suggestion:** Be precise with language. Milestones often require customized drafting.

DILIGENCE MILESTONES (REMEDIES)

ARTICLE 5: DILIGENCE

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5.3 LICENSEE shall achieve each MILESTONE on or before the deadline dates indicated. LICENSEE shall provide notice thereof to MICHIGAN within fourteen days after each such deadline as to whether or not such MILESTONE was met. If LICENSEE fails to accurately provide notice to MICHIGAN that it has failed to meet an applicable MILESTONE under this Article by the date of such MILESTONE deadline, LICENSEE shall be deemed to be in material breach of this Agreement. The parties agree that MICHIGAN's failure to provide notice of breach or initiation of breach proceedings under Article 11 or any other provision of this Agreement shall not operate as a waiver of, or estoppel as to, MICHIGAN's ability to do so at any time in the future, and any period of limitations that would otherwise apply shall be extended until for a period equal to the period of time from the MILESTONE deadline until the termination of this Agreement.

What Happens?

- ✓ **U-M Position:** There must be a mechanism for U-M to retrieve the IP if the licensee is failing to meet reasonable milestones.
  - Be clear about right to terminate.
- ✓ **Flexibility:**
  - One-time milestone extension fee
  - Convert to non-exclusive (not preferred)
- ✓ **It Matters:** 14 of our 40 startups in FY2026 licensed IP that had been previously licensed

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#5 BROAD ACCESS

Point 5

Ensure broad access to research tools.



Context

- ✓ **Mission:** To maximize positive societal impact – balance broad licensing with need for licensee to invest to bring tech to market.
- ✓ **Variety of Models:** Different technologies require different licensing models.

ENSURING BROAD ACCESS: NONEXCLUSIVITY

ARTICLE 2: GRANT OF RIGHTS

2.1 MICHIGAN hereby grants to LICENSEE a nonexclusive license under the PATENT RIGHTS, subject to the terms and conditions of this Agreement, in the FIELD OF USE and the TERRITORY to make, have made, import, use, market, offer for sale and sell LICENSED PRODUCTS.

Nonexclusive v. Exclusive

- ✓ **Last Fiscal Year:**
  - 197 nonexclusive licenses
  - 53 exclusive licenses
- ✓ **When Exclusivity Works:** When the amount of investment required to bring the product to market requires exclusivity.
- ✓ **Products**
  - 43 FDA Approved Products (2000)
  - 23 products in clinical trials

ENSURING BROAD ACCESS: EXAMPLE

A gene discovery that changed cystic fibrosis care, and genetic research, forever

"Gene hunting" approach developed by a U-M team led by Francis Collins, Ph.D., and their Canadian counterparts led to a new way of identifying disease-related genes

April 17, 2026 11:00 AM



Francis Collins, M.D., Ph.D., illustrating the "needle in a haystack" approach of hunting for disease genes using the approach that he and his co-discoverers developed and used to find the CF gene

CF Gene Patent Licensing

- ✓ **Nonexclusive:** Nonexclusive licensing employed to enable broad access
- ✓ **Fees:** Reasonable fee structure to allow in-house diagnostics
- ✓ **Inventor Input:** Significant input from inventor assisted in strategy
- ✓ NGOs: Partnered with OneWorldHealth to enable humanitarian licensing

ENSURING BROAD ACCESS: EULAS

END USER LICENSE AGREEMENT

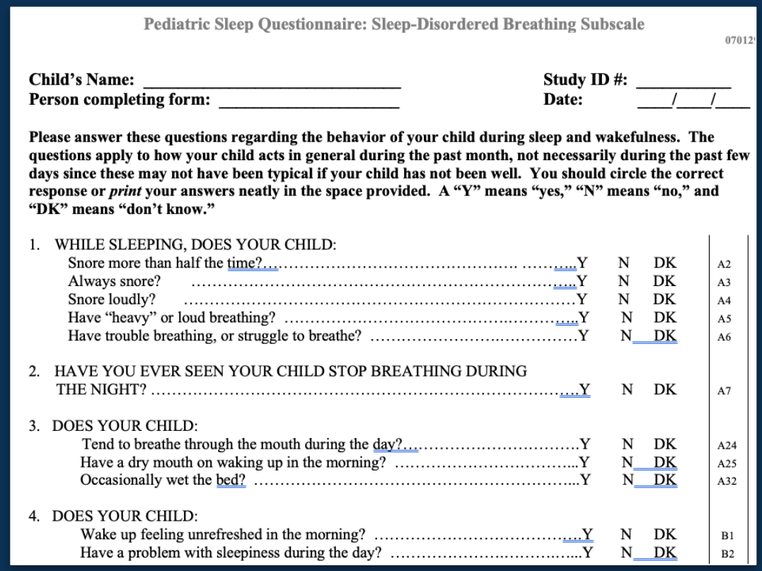
I. LICENSE

MICHIGAN hereby grants to LICENSEE a non-exclusive, non-transferable right to use the PROGRAM solely within the department or business unit listed above and subject to the terms and conditions of this Agreement.

II. LIMITATION OF LICENSE AND RESTRICTIONS

A. LICENSEE is granted the right to use the PROGRAM in a clinical trial and research studies under LICENSEE program support for the "Validation of Patient Reported Outcome Measures (PROMs) tools in Inherited Retinal Dystrophies (IRD)", Research Ethics Board Number 1000062319. The license allows for use with unlimited unique participants in the research protocol above (collectively referred toas "STUDY"). In connection with the STUDY, MICHIGAN hereby authorizes LICENSEE to modify and translate the PROGRAM as set forth in Exhibit A attached hereto. The PROGRAM shall be distributed by the department or business unit listed above or such department or business unit's designee to the participants enrolled in the STUDY at appropriate intervals during the term of this Agreement.

Patient Reported Outcomes



Pediatric Sleep Questionnaire: Sleep-Disordered Breathing Subscale

07012

Child's Name: _____ **Study ID #:** _____

Person completing form: _____ **Date:** ____/____/____

Please answer these questions regarding the behavior of your child during sleep and wakefulness. The questions apply to how your child acts in general during the past month, not necessarily during the past few days since these may not have been typical if your child has not been well. You should circle the correct response or *print* your answers neatly in the space provided. A "Y" means "yes," "N" means "no," and "DK" means "don't know."

1. WHILE SLEEPING, DOES YOUR CHILD:				
Snore more than half the time?	Y	N	DK	A2
Always snore?	Y	N	DK	A3
Snore loudly?	Y	N	DK	A4
Have "heavy" or loud breathing?	Y	N	DK	A5
Have trouble breathing, or struggle to breathe?	Y	N	DK	A6
2. HAVE YOU EVER SEEN YOUR CHILD STOP BREATHING DURING THE NIGHT?	Y	N	DK	A7
3. DOES YOUR CHILD:				
Tend to breathe through the mouth during the day?	Y	N	DK	A24
Have a dry mouth on waking up in the morning?	Y	N	DK	A25
Occasionally wet the bed?	Y	N	DK	A32
4. DOES YOUR CHILD:				
Wake up feeling unrefreshed in the morning?	Y	N	DK	B1
Have a problem with sleepiness during the day?	Y	N	DK	B2

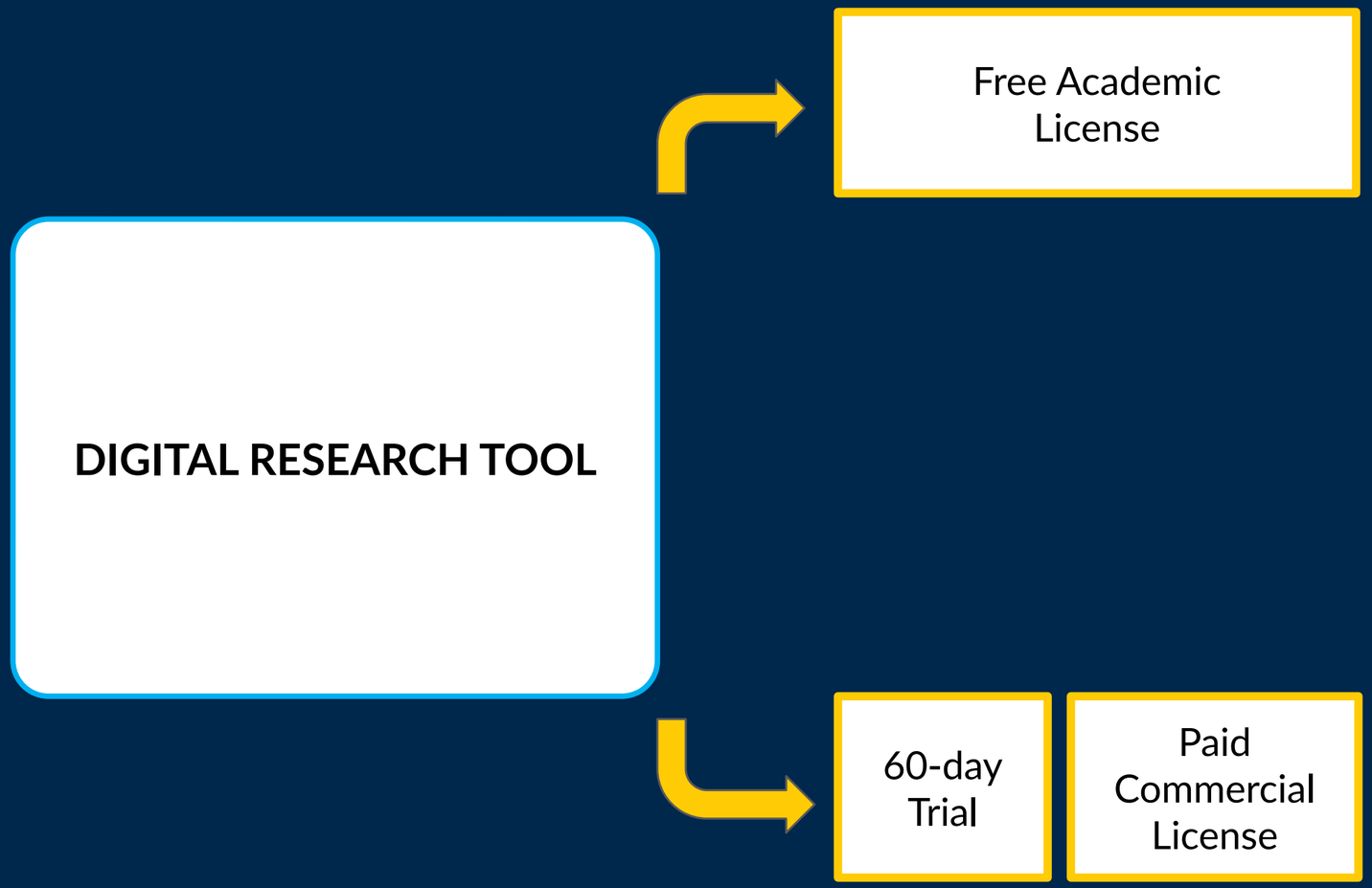
>1.5M patients

given a voice through UM patient reported outcomes" (last 10 yrs.)

30+ active patient reported outcomes

across multiple domains at UM

ENSURING BROAD ACCESS: DUAL TRACK



ENSURING BROAD ACCESS: FIELDS OF USE

ARTICLE 6: SUBLICENSES

6.5 If at any point after the second anniversary of the EFFECTIVE DATE, a third party ("Interested Third Party") notifies MICHIGAN of LICENSEE of its bona fide interest in commercializing LICENSED PRODUCTS in a field of use for which LICENSEE or a SUBLICENSEE is not then developing or selling LICENSED PRODUCTS ("New Field of Use"), MICHIGAN may provide written notice to LICENSEE specifically identifying such New Field of Use ("Interested Third Party Notice"). **Within sixty (60) days after such notice from MICHIGAN, LICENSEE shall provide written notice to MICHIGAN ("New Field of Use Election"), containing one of: (a) LICENSEE's written statement and documented evidence of its commercially reasonable efforts to develop a LICENSED PRODUCT for commercial use in the New Field of Use (to be reviewed and verified by MICHIGAN in its reasonable discretion); (b) LICENSEE's election to amend the "FIELD OF USE" definition hereunder to exclude the New Field of Use, to be negotiated in good faith by the Parties and documented within thirty (30) after the New Field of Use Election; (c) LICENSEE's election to negotiate in good faith with the Interested Third Party for an exclusive sublicense in the New Field of Use under commercially reasonable terms (to be completed within three (3) months after the New Field of Use Election); or (d) LICENSEE's election to enter into negotiations with MICHIGAN to amend the Agreement to include specific diligence terms specifically addressing and requiring the prompt development of LICENSED PRODUCTS in the New Field of Use (said amendment to be completed within three (3) months after the New Field of Use Election).** If the particular election in LICENSEE's New Field of Use election is not accepted (in the case of election (a)) or completed in the time period specified above despite the good faith efforts of MICHIGAN, then upon MICHIGAN'S ten (10) day written notice to LICENSEE, the "FIELD OF USE" definition hereunder shall be automatically amended to exclude the New Field of Use.

Unpursued Fields of Use

- ✓ **Common Issue**
  - University technologies often have multiple potential applications
  - Licensees initially want access to all fields of use
  - Universities want to ensure that any potential field of use can be pursued
- ✓ **Compromise:** Allows licensee to raise money & explore all fields of use; preserves ability to address a field of use when a viable third party is interested

OPEN SOURCE LICENSING SUPPORT



BONUS: SUPPORT SOCIAL IMPACT REGARDLESS OF ROI

U-M PRINCIPLE

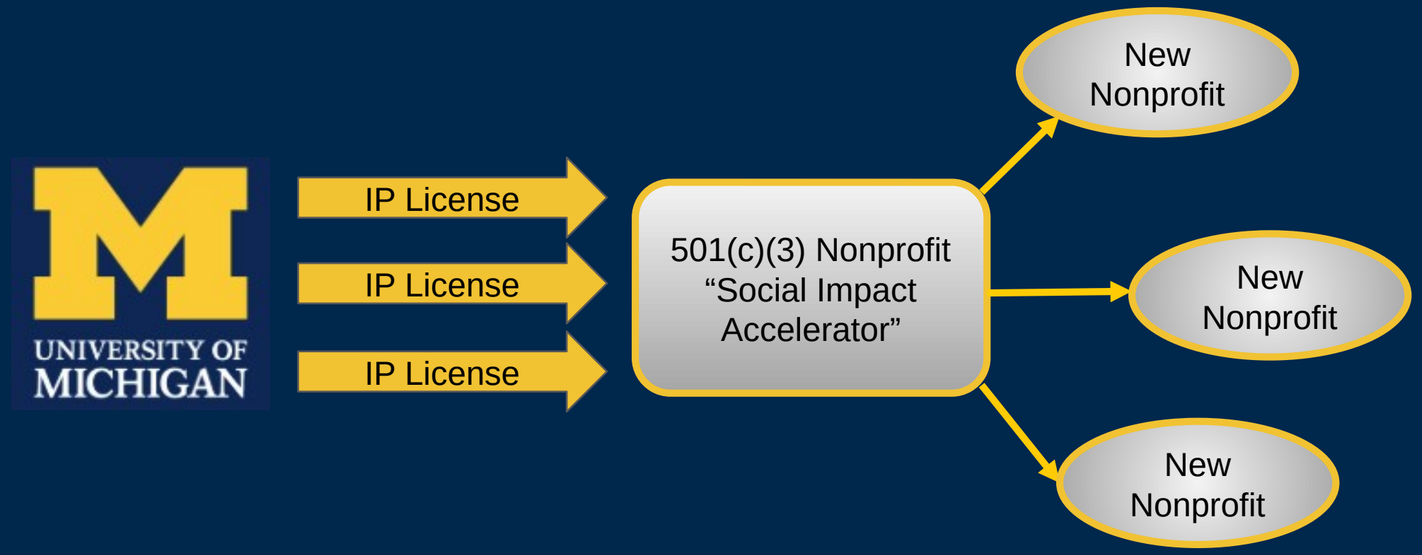
Support nonprofits and other social impact ventures regardless of the likelihood of licensing revenue providing a meaningful ROI.



Social Impact Toolkit

- ✓ **Stay or Go:** Support existing university centers in assessing the economics of spinning out.
- ✓ **Entity Selection:** Develop expertise around entity selection criteria for social enterprises.
- ✓ **Fiscal Sponsors:** Identify potential fiscal sponsors

U-M SOCIAL IMPACT ACCELERATOR



Example Projects

- ✓ **TRAILS:** Mental health counseling materials for high schools
- ✓ **Open Source Leg Project:** End-to-end open-source platform providing researchers with standardized hardware designs, software libraries, and documentation to ease development
- ✓ **Skiff & Schooners:** Interdisciplinary, grant-funded initiative that partners with regional organizations to reconnect communities with the river and its stories

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#9 UNMET NEEDS

Point 9

Consider including provisions that address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics and agricultural technologies for the developing world.



Approaches

- ✓ **Reserved Right:** Broad right, but only applies to licensed patents
- ✓ **Compulsory Sublicensing:** Typically only applies to licensed patents
- ✓ **Affordable Access Plans:** Modern approach pioneered by UCLA and Medicines Patent Pool

AFFORDABLE ACCESS PLANS

AAP Implementation

- ✓ **After Approval, Licensee Discloses:**
  - LMICs not being pursued
  - Actions to pursue LMICs
- ✓ **Why This Works:**
  - Information sharing
  - 77% of pharma uses Access Plans
  - Applies to the drug (not the patent)
- ✓ Adoption:
  - UM's last 15 exclusive therapeutics licenses
  - 8 funding rounds (>$100M raised)

4.7 LICENSEE shall provide to MICHIGAN an Affordable Access Plan of the scope set forth in this Section 4.7 within three (3) months after the first marketing approval of a LICENSED PRODUCT received by LICENSEE or a SUBLICENSEE from the U.S. Food and Drug Administration or the European Medicines Agency. LICENSEE agrees to use reasonable efforts to make progress toward completing the plans stated in the Affordable Access Plan, as it may be amended from time-to-time.

(a) "Affordable Access Plan" means a written statement setting forth: (a) the specific LMICs in which neither LICENSEE nor any SUBLICENSEE intends to commercialize the LICENSED PRODUCTS (the "Non-Commercialized Territories"); (b) actions to be taken by LICENSEE and, if applicable, SUBLICENSEE(s) that reasonably intended to support affordable access in the Non-Commercialized Territories by patients to products that would constitute LICENSED PRODUCTS if covered by one or more of the PATENT RIGHTS; and (c) actions to be taken by LICENSEE and, if applicable, SUBLICENSEE(s) that are reasonably intended to support affordable access for the vulnerable, underserved and special needs populations in the U.S. Such actions, as referred to above, shall at a minimum include strategies, such as licensing or partnerships (which may include, for example, partnerships with non-profit organizations), and timelines therefor. As used herein, "LMICs" means Low and Middle Income Countries as the term is defined and/or used by the World Bank Group, its primary recognized member organizations, and/or successor of any of the foregoing. Upon LICENSEE's request, MICHIGAN agrees to meet with LICENSEE to assist in the drafting of the Affordable Access Plan.

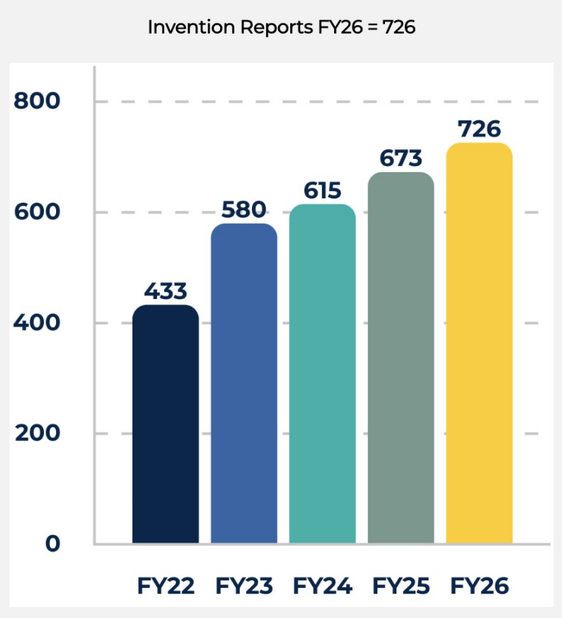
(b) Notwithstanding the foregoing, in lieu of providing an Affordable Access Plan, LICENSEE may instead submit a reasonably detailed written explanation as to why LICENSEE believes that an Affordable Access Plan is unreasonable or infeasible (the "Infeasibility Statement"), which is due on the same date that the Affordable Access Plan would have been due. After LICENSEE submits an Infeasibility Statement to MICHIGAN, LICENSEE agrees to promptly (but in no event less than two months thereafter) meet with MICHIGAN in person or by video conference to discuss the Infeasibility Statement (the "Initial Discussion"). If, following such meeting, MICHIGAN concludes that the Affordable Access Plan requirements of this Agreement are reasonable and desirable, LICENSEE shall nevertheless provide an Affordable Access Plan to MICHIGAN within three (3) months after MICHIGAN'S written request following the Initial Discussion (and, for clarity, the remaining provisions relating to the Affordable Access Plan shall apply).

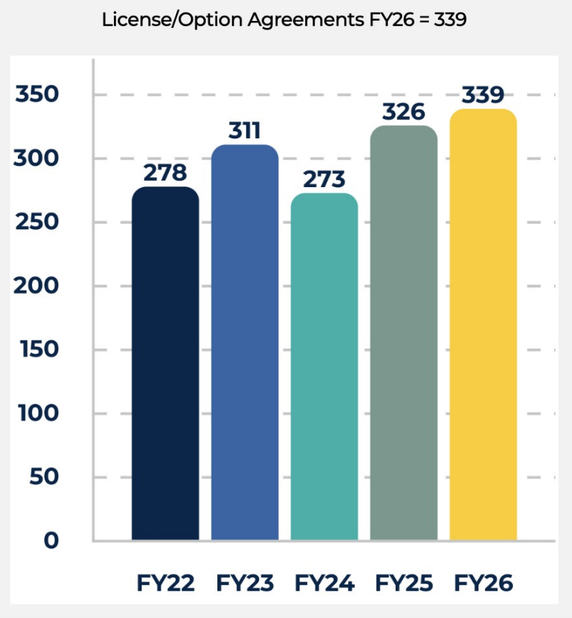
(c) If LICENSEE fails to follow any plan, take any action, or meet any milestone by a deadline that is specifically or generally stated in the Affordable Access Plan, it shall promptly and in good faith negotiate an amended Affordable Access Plan with MICHIGAN. In addition, within thirty (30) days after a request by MICHIGAN (but not to be requested any more than once in any calendar year), LICENSEE agrees to confer with MICHIGAN in good faith to review LICENSEE's progress, and to consider in good faith any reasonable modifications suggested by MICHIGAN concerning LICENSEE's Affordable Access Plan ("Progress Discussion"). MICHIGAN may invite a designated entity to join either the Initial Discussion or Progress Discussion, provided that such discussions shall at all times be made subject to the confidentiality obligations of this Agreement (or another mutually agreed-upon nondisclosure agreement).

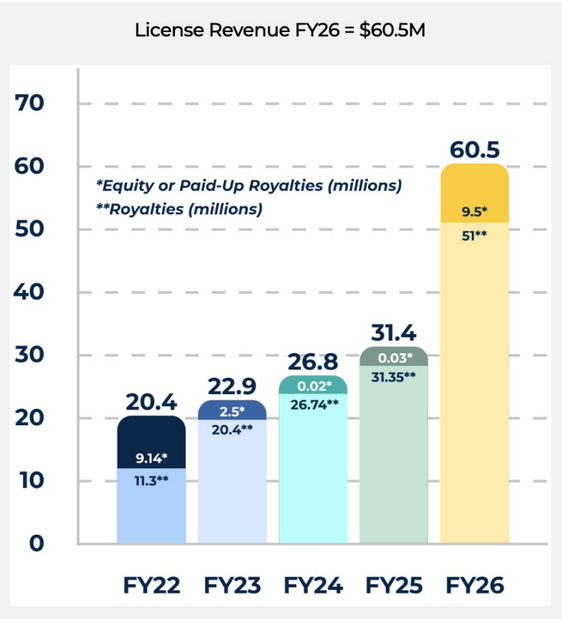
Socially Responsible Licensing is Good for Business

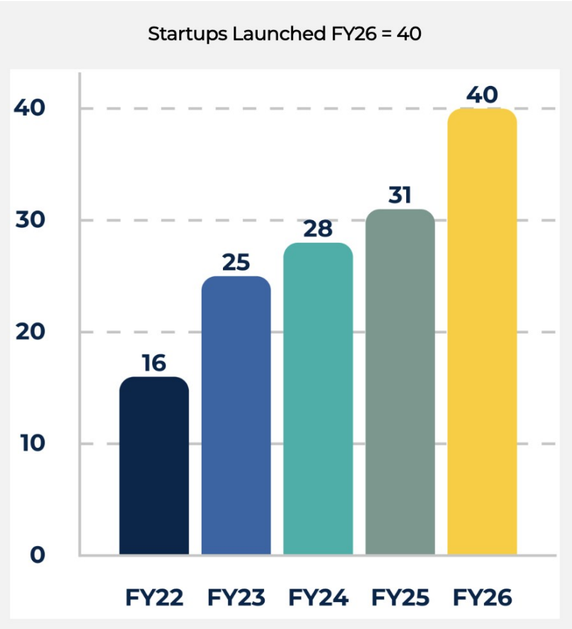
Late 2021:

- rebranded: **“Innovation Partnerships”**
- Mission → maximize positive **societal impact**
- Support for **non-profits** (social impact startups)
- **Open source** licensing











Thank you!

Questions?