BUSINESS MODEL INNOVATION IN START-UPS:

AN EXPLORATORY CASE STUDY OF WHY AND HOW BUSINESS MODELS ARE CHANGED

by © Blaine Edwards (Thesis) submitted

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Abstract

It has been long understood that start-ups change their business models. However, research on creating a business model, called business model development, and the change of business model, called business model innovation, has primarily focused on established firms. There is a lack of empirical evidence of why and how start-ups change their business model, and it is unclear to what extent existing literature on established firms can be applied to start-ups. The research question of this thesis is "Why and how do start-ups change their business models?". This thesis provides a unique contribution to the study of business model innovation by providing an exploratory case study of six versions of a start-up's business model canvas. While considering the impact of human capital investments and outcomes, it is shown that a) business models are changed because founders *believe* that the business model is not, or cannot be, profitable, OR that there is a more profitable and scalable option within reach, and b) business models are changed by discovering new markets or customer use cases and then arranging the resources, capabilities, network allies, and operations necessary to achieve the desired impact.

General Summary

This thesis is about why and how start-ups change their business models. It is focused on a start-up company called UnBound Chemicals that recycles ingredients from pharmaceutical waste. It describes the impact that training, mentorship, and meeting with experts and potential customers had on the evolution of the business model and shows six versions of a business model canvas.

Acknowledgments

First, I would like to thank my supervisor, Dr. Alex Stewart, for the encouragement to pursue the venture and the guidance to turn it into this thesis. I would also like to thank my wife and parents for supporting me through the process. Thanks finally to our Gordon setter, Marty, whose daily demands for his walk gave me a chance to ruminate. The cat contributed nothing.

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Chapter 1: Introduction

It is well known that start-ups change their business models, but much less known about why or how those changes take place (Foss & Saebi, 2017). This is challenging to explore because many start-ups disappear before they get a chance to be studied, resulting in most research on business model development and business model innovation being conducted on established firms or more firmly established start-ups (Aldrich & Yang, 2012).

In 2018, I founded UnBound Chemicals, a start-up that recycles ingredients from unused pharmaceuticals. I used the data from this first-hand experience to develop an exploratory historical case study on how the individual accounts influenced the development and innovation of the company's business model. That data was used to help answer the research question of this thesis, "Why and how do start-ups change their business models?".

Despite increasing recognition that business models are a valuable unit of analysis (Morris et al., 2005; Zott et al., 2011), few studies actually show multiple business models. A search of periodicals resulted in just two studies, Poláková et al. (2015) and Díaz- Díaz et al. (2017), both of which show two versions of a business model canvas. In contrast, this study provides six versions of a business model canvas, thus providing the opportunity to dive deeper into the phenomenon of business model innovation.

This paper proceeds as follows: First, I review definitions of entrepreneurial terms and review relevant literature on business models and human capital. Second, I review the methodology, including data collection and the frameworks for analysis. Third, I present data on the development of the initial business model and the five instances of business model innovation through first-hand accounts and multiple versions of business model canvases.

Fourth, I provide an analysis of the impact of individual accounts on business model innovation and subsequent changes to components of the business model canvas. Finally, I conclude with a summarisation of findings and a call for more research into start-up business model innovation.

Chapter 2: Literature Review

Definitions

Here, I offer some definitions of key terms and concepts that are used throughout the thesis.

Entrepreneurship is defined as "an activity that involves the discovery, evaluation, and exploitation of opportunities to introduce new goods or services, ways of organizing, markets, processes, and raw materials through organizing efforts that previously had not existed (Venkataraman, 1997, p.218).

Entrepreneurial opportunities are "those situations in which new goods, services, raw materials, and organising methods can be introduced and sold at a greater than their costs of production" (Shane & Venkataraman, 2000, p. 220).

Start-ups are "often technology or science-based companies with the potential to become large and valuable." They are led by **founders,** "those that start new organisations to pursue opportunities" (Wasserman, 2012, p.6). They differ from **established firms**, which already have a position in the market and are executing an existing business model (Blank, 2013).

Business models are "the design or architecture of the value creation, delivery, and capture mechanisms" of a firm (Foss & Saebi, 2017, p. 202) that "reflect management's hypothesis about

what customers want and how an enterprise can best meet those needs and get paid for doing so (Teece, 2010, p. 1329).

Business model innovation is the "designed, novel, non-trivial changes to key elements of a firm business model and/or the architecture linking these elements" (Foss & Saebi, 2017, p. 210)

Business Models

There is no universally accepted definition of a business model (Morris et al., 2005). However, the business model's focus on value makes the concept unique from business strategy (Massa et al., 2017). To elaborate on the above definition: A firm enables value *creation* through entrepreneurial activity, such as introducing an innovation (i.e., technology or service) or reorganising existing resources into new ways and providing them to customers (Venkataraman, 1997). Value *delivery* refers to the exchange between the firm and customers; it is how that innovation is made available to customers. Value *capture* focuses on how the firm is compensated. The "design or architecture" refers to the individual components of the business model and how they interact.

A *good* business model will address the matters of creation, delivery, and capture of value (Teece, 2010) and can create benefits beyond the sum of the individual components (Zott & Amit, 2007). For example, the clarity and guidance resulting from business models have been found to improve firm performance (Trimi & Berbegal-Mirabent, 2012). Managers and staff benefit when goals are clear, and everyone is on the same page. Other benefits stem from business models' role in realising value from innovation. First, technological innovations have little value on their own (Chesbrough, 2010). For instance, newly created software only benefits creators or customers once users adopt it. A business model is the vehicle in which to access technology's latent value (Chesbrough, 2010). If the same technology deployed through two

different business models would result in two different outcomes, then the value of the technology is also related to the quality of the business model (Chesbrough, 2010). Second, a good business model can itself be a source of sustainable competitive advantage (Massa et al.,2017). The stronger the ties between a firm and its customers, the harder it is for other firms to steal those customers (Bashir & Verma, 2017). Finally, the high-level perspective provided by business model thinking allows for a more holistic approach which can develop new sources of market demand (Massa et al., 2017).

Business Model Development

Business models can be developed by entrepreneurs or managers in start-ups or established firms. Business models in any firm have been found to contain similar components that answer questions about the core activity, including 1) factors relating to the offering (*how do they create value?),* 2) market factors (*who do they create value for?),* 3) internal capabilities (*what is their source of competence?),* 4) competitive strategy factors (*how do they competitively position themselves?*), 5) economic factors (*how do they make money?),* and 6) personal/investor factors (*what are their time, scope, and size ambitions*?) (Morris et al., 2005, p. 730). The value created at the intersection between the firm and the customer (called value proposition) is an essential concept (Oserwalder & Pigneur, 2010).

A "value proposition" is an understanding of *what* customers want, not what entrepreneurs *think* customers want. Unless an entrepreneur has sufficient experience and insight, the development of a value proposition requires an exchange of information between the firm and potential customers (Blank, 2013). Different strategies have been developed to facilitate the exchange of information between firms and customers so that value propositions can be tested and refined (Trimi & Berbegal-Mirabent, 2012). For example, the Open Business Model

(Chesbrough, 2007) advocates for firms to "open up" to the market to look for new and fresh ideas.

Business Model Canvasing (BMC) is a method of designing and testing value propositions and business models that was developed by Osterwalder and Pigneur (2010). It used conceptual representations (Massa et al., 2017), or a workshop-style canvas, of crucial components to help entrepreneurs design their business model and test hypotheses about overall profitability. The canvas is broken up into internal (key partners, key activities, essential resources, cost structure) and external (customer relationships, channels, customer segments, revenue streams) components, with value proposition(s) in the middle.

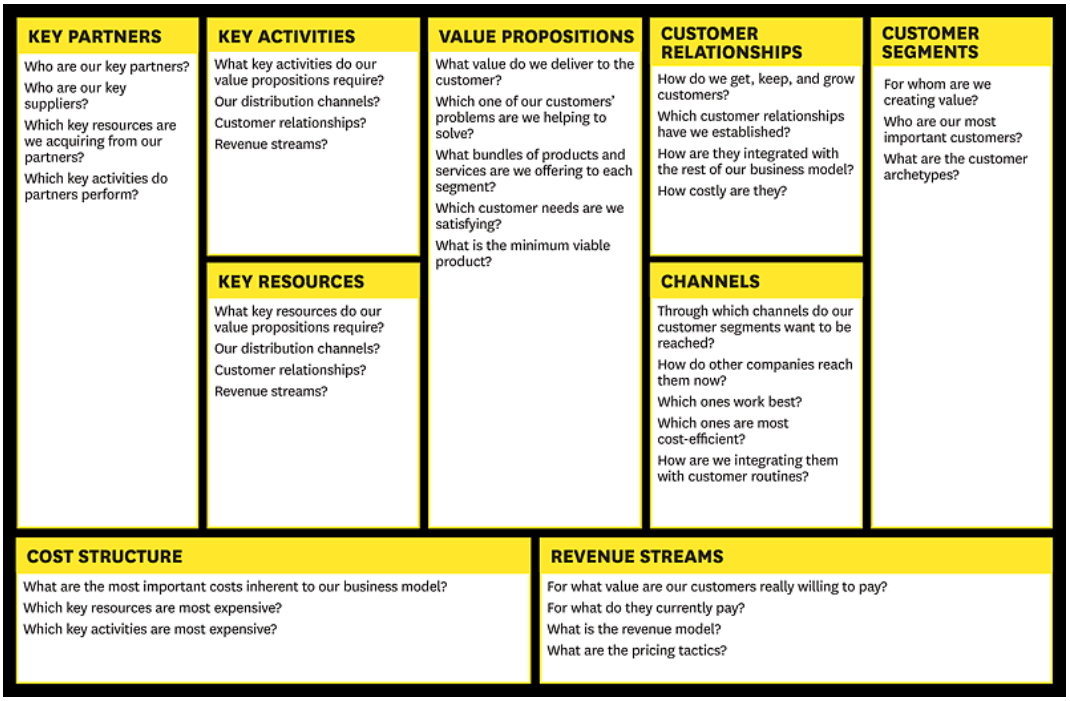

Figure 1: Lean Start-up Business Model Canvas

This style was adopted by Reis (2011) and Blank (2013) to create the Lean Startup® model method of business model design (Shepherd & Gruber, 2021). The Lean Startup® method combined the concepts of BMC, lean manufacturing, and validated learning to test business

hypothesis (Blank, 2013). The fundamentals of the method are taught to entrepreneurs worldwide and include:

1. **Business Model Canvas**: Rather than develop a rigid business plan, accept that there are assumptions and the plan will change, and use the BMC to map the development of a Minimal Viable Product (MVP)
2. **Listen to Customers:** Test your hypothesis with real customers and develop the MVP.
3. **Agile Development**: Change/pivot the MVP based on customer feedback.

Pivoting is defined as "a structured course correction designed to test a new fundamental hypothesis about a product, strategy, and engine growth" (Reis, 2011, p. 149) and is an integral part of business model development (Blank, 2013). When a person pivots, they spin to face a new direction while keeping the other foot firmly planted. The idea of pivoting a business model is similar. You can change the direction of the business by making modifications to some aspects while keeping others in place. However, knowing when and how to pivot is challenging for start-up founders, especially those with limited experience (Cohen et al., 2019). Founders often resist pivoting the value proposition despite receiving negative feedback and may develop "auxiliary hypotheses" for other components of the business model (BM) (Burnell et al., 2022, p. 14).

Business Model Innovation

Although we know that business model innovation (BMI) takes place, we still know very little about why or how it happens. While the previous section highlighted the importance of validated learning and pivoting during the business model development (BMD), the prerequisites, processes, and outcomes of BMI make it distinct from BMD (Schneider & Spieth, 2013).

Prerequisites: The extant BM is inherited from a firm's abilities and decisions of the past. However, circumstances change and the hypotheses that were made in the past regarding the creation, delivery, and capture of value may not be sustainable. BMI represents a firm's response to the uncertainty and change that exists within its environment (Schneider & Spieth, 2013, p. 21). Since BMI denotes that something about the BM has been decided to be changed it is unsurprising that the cognitive abilities of managers has emerged as an antecedent to BMI (Schneider & Spieth, 2013). Other environmental factors include external drivers such as strategic disruptions, intense global competition, competitive pressure, shifting consumer base, or other significant, unpredictable changes in the business environment or internal drivers such as strategy or dynamic capabilities (Foss & Saebi, 2017).

Process and Elements: Very little is known about how BMI is started or managed and how effective or ineffective BMI can impact established firms or start-ups. Research has been limited to a) the importance of idea generation and b) that BMI should be a continual process for firms (Schneider & Spieth, 2013). There are some examples of how BMI has been used to introduce greener and more environmental sustainable business practices (Geissdoeerfer et al., 2018)

Effects: The research into the effects of BMI has been shown to change market structures, financial results of firms, and firm capabilities (Schneider & Spieth, 2013).

Barriers to BMI are confusion and obstruction (Chesbrough, 2010). Confusion refers to the importance of cognitive abilities to acquire and accurately process relevant information. Obstruction refers to the resistance to change in organisations, called structural inertia.

During BMI, the business model is the focus of innovation rather than a particular product or service (George and Bock, 2011, as cited in Vittori et al., 2022). The context of the firm (incumbent, high tech, traditional, young, old, and single industry or diversified, etc.) is an important consideration (Foss & Saebi, 2017). Therefore, they require separate theoretical groundings. Schneider and Spieth (2013) argue that BMD has a theoretical grounding in Resource Based View/Dynamic Capabilities since it incorporates the Valuable, Rare, Imitable, and Non-substitutable (VRIN) resources as competitive advantages and the dynamic capability of renewing VRIN over time. In contrast, BMI requires entrepreneurial activity to seek and take advantage of opportunities that are better suited to be grounded in the theory of strategic entrepreneurship (see figure below).

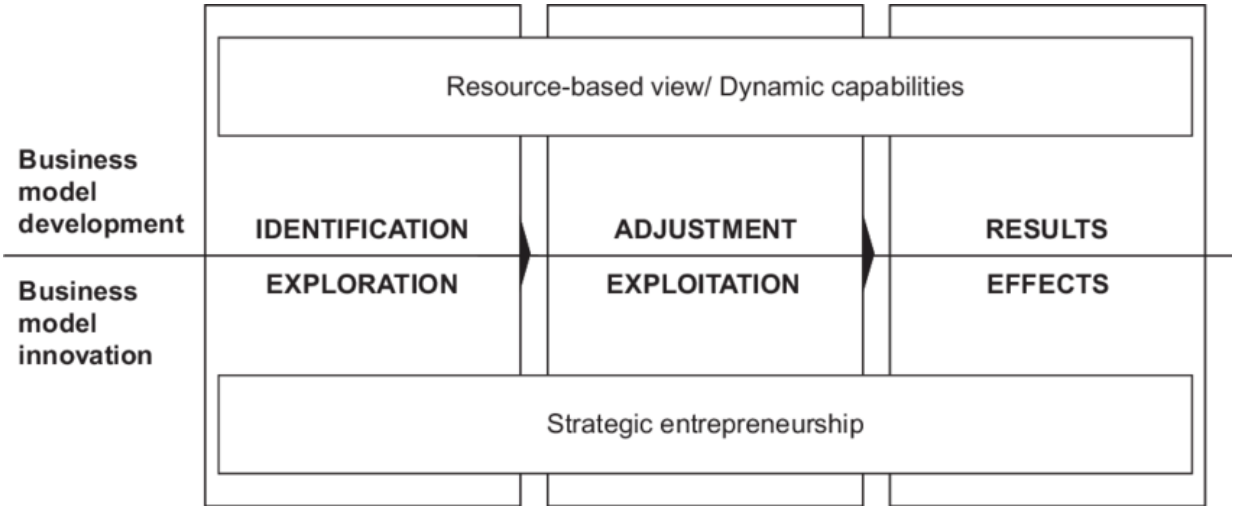

Figure 2: Theoretical Frameworks for BMC vs BMI (Schneider & Spieth, 2013)

Human Capital

Human capital is the collection of knowledge, skills, education, experience, and overall cognitive abilities that an individual brings to a task (Becker, 1975). The basic tenet of human

capital theory is that the more specific human capital one has concerning a particular task, the better one can perform that task (Becker, 1975). Human capital can take the form of human capital investments or human capital outcomes. Human capital investments provide access to human capital, such as education, training, experience, or recruitment while human capital outcomes refer to the knowledge, skills, and abilities that result from human capital investment (Marvel et al., 2016).

Human capital has been a useful construct for the study of entrepreneurship (Marvel et al., 2016). It has been found that entrepreneurs will gravitate towards opportunities that are a good fit for them as individuals and that their experience impacts their recognition and confidence of bringing an opportunity fruition (Davidsson & Honig, 2003; Shane, 2005). But the level of human capital has an impact on entrepreneurial success. For example, individuals with higher levels of relevant industry or previous entrepreneurial experience have been found to have a higher chance of successful venture activity (Davidsson & Honig, 2003).

Human capital can be deliberately developed (Schultz, 1961). For example, those who wish to improve their entrepreneurial skills can partake in training programs, which have been found to enhance the performance of new entrepreneurs (Martin et al., 2013). However, human capital outcomes were found to be better at predicting entrepreneurial success than human capital investments (Unger et al., 2011, as cited in Marvel et al., 2016). In other words, those with higher knowledge, skills, and abilities performed better as entrepreneurs than those with education, training, or experience alone. Even though two individuals may have similar education or experience, their skills and abilities may differ (Keith and Frese, 2005).

Literature Review Summary

The concepts of entrepreneurship and business models are intertwined because, in essence, entrepreneurial activity involves the creation and execution of a business model (Teece, 2010). In fact, approaching entrepreneurship through the study of business models can provide valuable insight (Zott, et al, 2011).

Business model development and business model innovation are unique concepts that have separate theoretical foundations (Schneider & Spieth, 2013). A different approach is needed when creating something new, compared to modifying something that already exists. Even the recognition that a business model should be changed can be a difficult arrival. Nonetheless, the business model canvass has emerged as the predominate tool for start-ups to design and test hypotheses, document results, and convey and conceptualise ideas to others. Despite this potential, the literature has not made full use of the business model canvas as a way to measure and study business model development or business model innovation.

Finally, an entrepreneur's ability to develop or innovate a business model depends largely on their individual skills and experience. The theory of human capital helps explain the perceived subjective value of entrepreneurial opportunities and how one's background can impact success.

Chapter 3: Methodology

This thesis is a qualitative study on why and how start-ups change thieir business models. It is an exploratory study that uses the qualitative methods of historical case study and auto-

ethnography and is based on archival records augmented by reflections of the founder (your author). This section will review the methodology, data collection, and analytical framework used. The selection of a case study is particularly suitable for this thesis. The case study is most helpful in generating hypotheses for lesser known phenomena (Flyvbjerg, 2006), which fits since little is known about how entrepreneurs develop or innovate business models (Foss & Saebi, 2017).

Qualitative Methods

Qualitative research methods are used to go deep into issues. Case studies are a form of qualitative research that involves the "intensive study of a single unit for the purpose of understanding a larger class of (similar) units… observed at a single point in time or over some delimited period of time (Gerring, 2004, p. 342, as cited in Baškarada, 2014). A case study provides an opportunity to deeply understand a research problem or situation (Flyvbjerg, 2006). In keeping with exploratory case studies and grounded theory, the formation of the research question came after the review of the data. (Baškarada, 2014).

The auto-ethnographic contribution of personal reflections is also suitable for studying entrepreneurship because it can go deeper than traditional structured interviews or database analysis (Briody & Stewart, 2019). Self-observation as a data collection technique, like that collected through auto-ethnography, is helpful because it gives access to "covert, elusive, and personal experiences such as cognitive processes, emotions, motives, concealed actions, omitted actions, and socially restricted activities (Rodriguez & Ryave, 2002, p. 3).

Study Design

Site

The site studied is a start-up undergoing opportunity identification, business model development, and subsequent business model innovation. At the beginning of the study, the company had no revenue, no employees, and no proof-of-concept. The lead entrepreneur was the only individual involved in the project and was responsible for aspects regarding discovery, exploration, and execution.

Unit of Analysis

The case under study is start-up business model innovation. The units of analysis are the six business models and the individual accounts, including documents, communication, meetings, processes, and personal insights that influenced the business model.

Data Collection

The raw data for this thesis was from the material collected during business model development and business model innovation. This includes information collected through market and scientific research, industry informants, training programs, and formal education. It included 225 emails, eight versions of presentations, various business documents such as marketing plans and research reports, 40 meeting notes, 70 journal articles, 88 calendar entries, 1,150 pages of handwritten notes, and memories of interactions with numerous individuals. I provided personal reflections on accounts based on memory. During the business modeling process, I filled four notebooks with 1,150 pages of handwritten notes, which proved helpful in avoiding memory

decay. An estimated 125 individuals contributed to the process between 2016 and 2022. The names of individuals and companies have been omitted to maintain confidentiality.

Data Preparation

Business model canvases were selected as the descriptive framework. The business models in this thesis are displayed on a modified version of the Lean Startup® canvas developed by my entrepreneurship professor and supervisor, Dr. Alex Stewart (Figure 3).

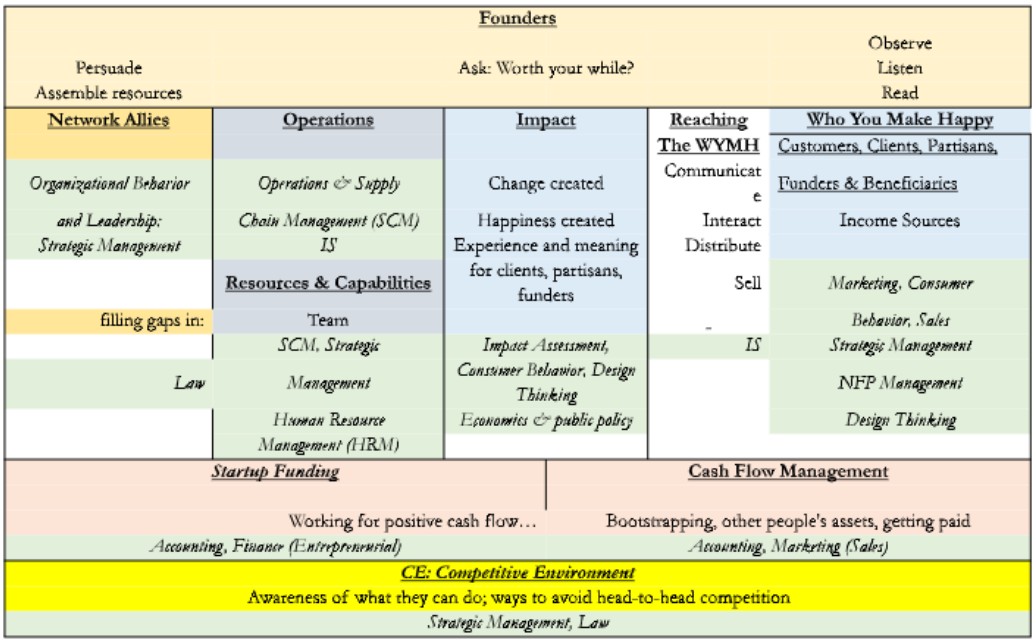

Figure 3: Business Model Canvas by Dr. A. Stewart

This version added the components of "Network Allies" and "Resources & Capabilities" to the canvas. These components were not directly addressed in the Lean Startup BMC but are

important considerations for start-ups. The section Who You Make Happy (WYMH) was added and helped narrow focus down to the individual level.

In the field, venturing activity and business model innovation was continuous. There was no reason to maintain separate versions of BMCs. Instead, information was rewritten over old entries or not documented at all. Therefore, for the first round of analysis, each activity was reviewed and coded based on the value proposition it supported to create separate business model canvases. Six unique business models emerged from the data:

1. Post-Consumer Waste Recovery (Early)
2. Post-Consumer Waste Recovery
3. Production Waste Recovery
4. Distributor Waste Recovery
5. R&D Waste Recovery
6. Negative Reaction Data, Machine Learning, and Computer-Assisted Synthesis Planning (CASP)

Accounts are the written summaries of a single interaction, a group of interactions, or an ongoing relationship. The accounts were written using calendar entries, notes, reference documents, and memory. They are presented in first person narrative since the author was the founder and could offer personal reflections on each account.

Account Selection

A total of 385 accounts were identified. Theoretical sampling aims to gain a deep understanding of the case, not a quantitative analysis of every case (Glaser & Strauss, 1967), so

only accounts that impacted the business model were included. A total of 25 accounts were created based on their impact on the development or innovation of the business model. The known theoretical elements of business model development, innovation, and human capital helped inform the selection. To be included, the account must have been directed related to the modification one or more business model canvas components.

Limitations

Since qualitative research occurs in a natural setting, there are inherent limitations of validity and reliability in all qualitative studies (Baskarada, 2014). The limited scope of data may also pose a problem since some data sources were incomplete or inaccessible. Triangulation, the process of using multiple data sources to verify an observation (Denshire & Lee, 2013), may not be possible. There are also gaps in the data, like between March - April 2021, where little was recorded due to competing priorities.

Case studies are highly focused and in-depth studies that can be of limited use in making general inferences about larger groups (Tsang, 2014). Case studies may uncover behaviour that is present in other organisations, but further research would be necessary.

There may be bias in the selection of accounts. The reader should not assume that only the provided accounts impacted business model development. Over seven years, thousands of interactions with family, friends, and colleagues went unrecorded, which may have unconsciously impacted my decision-making. Many of these were not documented or were not documented with the same level of detail. For example, some meetings were recorded with transcripts, and some had no notes. Therefore, important context may suffer from memory

decay. Similarly, hindsight bias can impact ethnographic studies. The fact that the outcome is known to the author while writing may have impacted the selection and omission of key events.

The business model canvases used to describe and assess different business models are imperfect representations since they were developed after they may not contain all the relevant data and represent the best picture possible at the time of creation.

Data Analysis

There were three phases of analysis. The first round included reviewing individual accounts to assess and measure their impact on the business model. The second round reviewed the modifications made to the six business models by analysing how the components of the business model canvas changed in response to new information. The third analysis phase was a round of deductive coding to search for themes from the data.

Business Model Analysis

The BMCs listed the activity, or planned activity, that corresponded with each business model. If a component was changed during business model innovation, the nature and extent of the change were noted. For the analysis, the changes in components were compared to previous changes of the same component and changes of other components in the same business model.

Account Analysis

Different accounts impact different components of the business model. A framework for quantifying the impact that each account had on the business model was required for analysis. The selected framework was developed based on my own set of pre-determined success criteria.

During the first round of analysis, I uncovered a handwritten set of success criteria that I had developed before I incorporated the company. I created this criterion to focus my efforts and serve as a health monitor. If there were signs that one of these elements was not achievable, then I would abandon the project. The criteria were inspired by the VRIN model (Barney, 1991), which I had learned about during my master's program. The criteria included:

- **Viability:** The project was achievable regarding regulations, waste availability, and human resources.
- **Technology:** A process that could successfully recover targeted ingredients from a waste source.
- **Intellectual property:** Novel technology or processes that would give the company an element of exclusivity and competitive advantage.
- **Profitability:** The material could be recovered for less cost than it could be resold.
- **Scalability:** The solution solved a problem faced by multiple organizations in the marketplace and could be captured with a non-linear investment.

Each account was assessed based on the above criteria. The level of impact was scored in three ways: positive (+), neutral (/), or negative (-). A positive impact would mean that the account provided information, feedback, or proof that the criterion was achievable and, therefore, I should keep going (Dimov, 2010). A neutral score indicated that the account had no impact or was irrelevant. A negative impact meant that the account provided information, feedback, or proof that the criteria were not achievable. Note that the assessment of the first business canvas (Business Model A(i)) does not include success criteria because this model pre-dates the success criteria.

Thematic Coding

The third round applied the technique of coding to identify emergent themes from the data. Grounded theory is a qualitative method of analysis where themes and hypotheses emerge from reviewing qualitative data rather than establishing a hypothesis upfront (Glaser, 1967). This round was an open round of inductive coding where the author did not use a pre-established set of codes. However, the coding was guided by established theory on business model development, business model innovation, and entrepreneurial human capital.

Chapter 4: Business Model Data

This section will present the data (accounts and business model canvases) involved in business model development and innovation. First, I review the relevant background to developing the first business model, including how the opportunity was discovered, the early venturing activity, and the decision to pursue it. Then, I outline the business models and the accounts that brought about business model innovation, why they brought about change, and how that change was made.

Business Model Development: Business Model A(i)

This section reviews the discovery of the opportunity and the creation of the initial business model canvas.

<table>
<tr><td colspan="5">Founders and Contributors
Blaine Edwards</td></tr>
<tr><td>Network Allies

Community pharmacies pharmcy chains?
Waste management non-profits (MMSB)
Wate managemnet companies</td><td>Operations
Collect: form partnerships with hospitals and pharmacies that can provide raw material.
Sort: Sort medical waste based on potentiual value. Knowledge of drug value, and chemical value is needed.
Extract and Sell: Extract chemicals using designed process.</td><td>Impact

Reduce medicine waste in environment
Reduce cost of medical waste disposal

Incentivse people to return medication to pharmacies</td><td>Reaching Customers
Direct sales to researchers and university profs.
ecommerce site (www.labfill.com) to help with sales</td><td>Who You Make Happy

University profs and students get to do more of what they love: lab research.</td></tr>
<tr><td colspan="5">Resources and Capabilities
Scientific know-how
Project and people Management
Diverse, knowledgeable team</td></tr>
<tr><td colspan="3">Startup Funding
Funding and grant programs that match investments
Hacking Health ($900)</td><td colspan="2">Cash Flows
Revenue from selling chemicals</td></tr>
<tr><td colspan="5">Competitive Environment
Waste management firms (stericycle, WM)
Lab Chemical Manufactures
Lab Chemical Resellers
Residential toilet (where most people discard their pills)
Local hazardous waste collection agencies</td></tr>
</table>

Figure 4: Business Model Canvas A(i)

1.1 Opportunity Discovery

I first came across the issue of unused pharmaceuticals in March 2015. I read an article on the CBC website that reported that 20,000 pills had been returned to the annual pill drop held by the local police force (Quinn, 2012). The article noted that the medications would be brought to a "drug recycling company to be safely destroyed." Intrigued by the use of the word "recycling," I began researching via Google to learn where, how, and why medications were recycled. This quickly revealed that unused medications were not recycled in the traditional sense, like how aluminium cans are collected, melted, and reused. Regulations prohibit selling, donating, or sharing medications that were already dispensed or when their chain of custody by authorised professionals could not be verified (World Health Organisation, 2011). The World Health Organisation (WHO) developed standards regarding the donation of medications in 1996 and continues to prohibit the unsolicited donation of unused medication from individuals to developing countries (World Health Organisation, 2011).

However, I did discover news articles and research papers by pharmacists and chemists stating that the individual ingredients used to make medications, such as the active pharmaceutical ingredients (API), remain stable well beyond the labeled expiry date (Zilker et al., 2019) and could be recovered (Pratama et al., 2020) and reused (Sharma et al., 2019).

The volume of pharmaceuticals that go unused by patients per year remains very high. A 2015 study found that in the United States (US), an estimated 45% of prescription medications go unused by patients and calculated the retail value of the discarded portion to be $5.4 billion (Law et al., 2015). The API is the most valuable ingredient in medication, ranging from 3%-10% of the production cost (Pollak, 2011). The wholesale value of the active ingredients discarded in the US was estimated to be $250 million. I thought that if medications could be collected and the

main ingredients could be extracted at scale, then the ingredients could be resold to manufacturers to produce new medications.

1.2 Start Master's Degree

In 2017, I began a Master of Science (Management) degree from Memorial University of Newfoundland. My public service career had hit a ceiling, and a Master's degree would help career advancement. I strategically chose this program because it was offered by the Faculty of Business and allowed research into different sectors, unlike the MBA program, which was largely predetermined coursework. This would be a good opportunity to learn more about the commercialization of scientific research, pharmaceutical, and biotechnology industries. I would tailor most of my course work in this area to build a base of understanding.

In January 2018, I enrolled in an elective class on entrepreneurship. We were encouraged to select and work on a start-up idea. I selected the pharmaceutical ingredient recovery idea. My entrepreneurship professor was very encouraging, partly because it was different from the other ideas that my classmates chose and also because his family had extensive experience in the pharmaceutical industry. He knew that the industry was incredibly wasteful.

Enrolling in the entrepreneurship class gave me a real reason to research the opportunity's viability, establish boundaries to the idea, and complete the first business model canvas (Business Model Canvas A(i)). It also held me accountable to complete the tasks within a deadline since the course was three months long.

The model was built on my initial vision that began in 2016: collect unused pills from people and pharmacies, sort them using machinery, extract the valuable ingredients, and resell them to *someone*.

1.3 Start-up Training

I have always been interested in entrepreneurship. While in junior high, I completed a business plan for a paintball park as a hobby. It never went anywhere, but I enjoyed planning and combining all the pieces. In 2008, I got a public service job but always had the entrepreneurial itch. In 2013, I started a company that licensed popular European soccer team merchandise in Canada, USA, and Mexico. Three years later, I founded a non-profit website connecting inshore fishermen with customers and restaurants to sell fish. However, I was unfamiliar with how new technology was developed or how to build a larger business than myself. So, I began engaging with the University's entrepreneurship ecosystem. You could attend various programs to help design business models and help launch profit or non-profit projects. In the Fall of 2018, I enrolled in Genesis Evolution, a technology start-up education program that sought to teach early-stage entrepreneurs how to validate their business ideas. During the program, we were encouraged to connect with 100 people about our business, learn from them, and determine whether there was potential demand for your idea. However, there was no pharmaceutical industry in the region, so I only managed to contact 15 people. Most of them were industry-adjacent and were not knowledgeable industry experts. For example, some were pharmacists with some knowledge of the production process or employees of pharmaceutical companies such as sales representatives or regulatory experts well outside the R&D or production process. At the early stage, there was always an element of fear about talking to an expert because they could tell you that "your idea won't work." Part of me wanted to avoid those conversations and just enjoy the positive start-up atmosphere. Despite being unable to contact many people in the industry, the ecosystem was very supportive and encouraged me to continue pursuing the project.

1.4 Early Network

One of my first industry contacts a consultant contracted by a local health-tech accelerator. He had a background in health technology investment and was knowledgeable about the biotechnology industry, research, and start-up investing. At our first meeting, he was incredibly supportive of the business case: "Blaine, I think that this can make you a lot of money with this idea." I took this insight at face value even though I knew little about running a start-up or commercialising technology. But he crucially introduced me to his brother, who worked for a large biotechnology company in the US. His initial feedback was positive, and he informed me that the ingredients they bought or developed were very expensive, "and if you could reuse them, you could conceivably save some R&D time." He used a lot of acronyms and jargon, so I did not understand much of what he was talking about because I was still learning about the industry. Nonetheless, it was mostly positive, so it was enough to keep going.

1.5 Pitch Competitions

The start-up ecosystem in the area offered several pitch workshops and competitions. Genesis Evolution, my first training program, concluded with a pitch competition where each entrepreneur would pitch their business idea to a room of guests. I was a natural public speaker and was able to recruit further advisors and support for the project. The ecosystem was also eager to promote start-up activity in the life sciences.

In April 2019, I placed first in the Mel Woodward Cup, a pitch competition for the local ecosystem. The award was $10,000. This money was used to attend two pharmaceutical conferences, continue market research, and complete the first business model canvas. I was confident that it was achievable. I also believed I had the skills to assemble the necessary

resources. Having achieved satisfactory confidence, I pursued the opportunity by incorporating UnBound Chemicals Inc (UnBound) in May 2019.

Success Criteria

There were still more questions than answers. But what I had uncovered so far seemed positive. In April 2019, I noted several key questions that had to be answered. I refined them down to five components as outlined in figure 4.

Success Criteria	Criteria Description	At the time of the Founding
Viability	The project was achievable regarding regulations, waste availability, and human resources.	At this stage, I had anecdotal evidence that access to material, human resources, and laboratory facilities was possible. The regulatory component was not clear.
Technology	A process that could successfully recover targeted ingredients from a waste source.	I was satisfied that the necessary scientific process was readily available.
Intellectual Property:	Novel technology or processes that would give the company an element of exclusivity and competitive advantage.	This was not clear at this stage. However, I was comforted that a novel process could not be developed through literature alone and that time in the lab was necessary.
Profitability	The material could be recovered and sold for less cost than it could be developed through traditional means.	This was also unknown. However, the anecdotal accounts about the high value of research chemicals did provide some evidence that it was possible. Similarly, my research into the gram-level value of APIs made me believe this was possible.
Scalability	The solution solved a problem faced by multiple organisations in the marketplace and could be addressed with a non-linear investment.	This was also not known. However, initial research into the research chemical market showed that it was possible.

Figure 5: Success Criteria at Founding

Business Model A: Post-Consumer Waste Recovery

Business Model Summary
Value Proposition: Collect, sort, extract, and resell APIs from unused pharmaceuticals and resell them to researchers.
Duration: 54 weeks (April 2016- October 2021)
Outbound actions: 122
Scheduled events: 85

Founders and Contributors				
Blaine Edwards, Analytical Chemist, Chemistry Professor				
Network Allies	**Operations**	**Impact**	**Reaching Customers**	**Who You Make Happy**
1. Community Pharmacies 2. Waste management company 3. Startup ecosystem 4. Memorial university	1. Collect waste from pharmacies 2. Sort waste at our lab.	1. Reduce pharmaceutical waste in the environment 2. Reduce cost of medical waste disposal costs 3. Source of research material for researchers	1. Direct sales to researchers 2. ecommerce sales	1. Researchers (university professors and students) who get to do what they love: research 2. Pharmacy owners by reducing disposal costs.
Resources and Capabilities				
1. Extraction process for each active ingredient 2. Waste sorting technology 3. Collection of waste from key sources				
Startup Funding			**Cash Flows**	
1. Mel Woodward Pitch Competition ($10,000) 2. Genesis MicroFund ($20,000) 3. Greenfund Canada ($12,000) 4. National Research Council ($80,000)			1. Chemical sales 2. Subscription fees	
Competitive Environment				
1. Waste management disposal companies 2. Laboratory chemical suppliers 3. Residential toilet (where most people discard waste)				

Figure 6: Business Model Canvas A

Business Model A: Impact of Accounts on Success Criteria

No.	Item	Description	Success Criteria				
			V	T	IP	P	S
A.1	Chemistry Research Project	A trusted source of knowledge who was willing to be an ally to provide insight into the unknown, which provided an increased level of confidence.	+	+	/	+	/
A.2	Startup Ecosystem	The start-up ecosystem provided me with training, encouragement, and a low-risk playground to develop new skills.	+	/	/	+	+
A.3	Pharmacy Agreed to Share Material	The first instance of successfully recruiting a third party to support the project increased.	+	/	/	+	+
A.4	Scientific Validation	Completion of science research experiment that resulted in the validation of our extraction process.	+	+	+	+	/
A.5	Automated Sorting Machine	This is an example of what happens when resources are dedicated to business models that have not been fully evaluated.	/	-	+	+	-
A.6	Meeting with Pharmacy Professor	Received candid and negative feedback from a reliable source about the unfeasibility of the opportunity.	-	/	/	-	-
A.7	CDL	Impact of enrollment in the technology-focused mentorship program.	/	/	/	+	+
A.8	Investor Feedback	Guidance from an experienced investor.	-	/	/	-	-

Figure 7: Account Impact Scoring Business Model A

A.1 Chemistry Research Project

A chemistry professor at Memorial University also encouraged me to pursue this project. There were three main factors to their influence. The first was their reassurance that it was possible to recover the material. I did not have a chemistry background so I took this at face value. This was important because the project would stop dead in its tracks without the reassurance that it was scientifically possible.

The second is that she was actively engaged in a research project that required the research chemical *everolimus. Everolimus* is an active pharmaceutical ingredient in a cancer medication. A quick Google found that this API could be purchased from online research chemical suppliers for CAD 1100 per gram. The average dose was 500 mg per tablet. Therefore, if we could get just two tablets, we could recover enough of the API from the unused medication to supply her research group and save thousands of dollars.

The third influence was an introduction to a contact of hers who owned and operated a research supply company. He was also intrigued by the prospect of accessing high-value research material at a lower cost. He also informed me that pharmaceutical researchers followed a different set of less stringent regulations since the material they work with is limited to their laboratories and not yet intended for human use.

This assured me from a reliable source that three project areas were (theoretically) achievable: It was viable because the regulations allow for recovery and use so long as the material met minimum standards. The chemistry faculty had the facilities and expertise available to complete the project. The technology was achievable, and the project's profitability was possible since the cost of virgin material was higher than the inputs. However, the intellectual property and scalability of the project remained unknown.

A.2 Start-up Incubation & Funding

In April 2020, I was accepted into Genesis Enterprise's start-up incubation program and received $20,000 seed money to begin the project. In exchange for the $20,000, Genesis received a promissory note for $500,000 should the company succeed and would have to start being repaid once the company began generating annual revenue of $1 million.

The seed money was leveraged with government grant money to fund two positions to help progress the project. I could pull a small salary from the fund to dedicate myself to the project full-time.

The technological research of the project was funded through MITACS, a non-profit that provides funding for innovative research. This further extended the runway for research. With this funding, I was able to hire a postdoctoral analytical chemist who would complete the first laboratory research on APIs from unused pharmaceuticals. By June 2020, the project had $120,000 of non-dilutive funding to complete the proof-of-concept project.

A downside was that the incubation program was mostly filled with software or hardware start-ups. Their success was measured by the number of users, staff, and/or status of their technology. Although the staff were encouraging and helpful, I felt out of place. It became clearer that the performance indicators differed for early-stage, science-based companies. Wanting to show progress, I succumbed to the pressure and used some seed money to hire a marketing staff member to demonstrate progress to the governing committee. It was nice to have another person to work with. However, the marketing work they completed, while helpful, was not necessary for a company at such an early stage.

A.3 Pharmacy Provided Unused Medication

For any research to take place, we needed unused prescription pharmaceuticals. A professor at the Faculty of Pharmacy was able to make introductions to community pharmacists within driving distance. They regularly review their inventory and remove expired and near-expired medication before they order new stock. We asked them to put aside the medications, and I would pick them up.

Local pharmacies quickly agreed to provide test material. This was much easier than I anticipated. Since a University sponsored the recovery project, federal legislation allowed our project team to handle unused medications so long as they were not scheduled (ex. codeine). The initial batch contained 28 types of medication of varying quantities. They were all expired or near expired and were generic versions of off-patent medication. However, it quickly became clear that the waste did not meet demand. What was discarded was the lower-value medication that was not being used in research. Unfortunately, we could not obtain any *everolimus,* the API the local chemistry group required. Furthermore, the waste was mixed and unorganized. Thousands of individual tablets and pills were dumped into containers and packaging of different sizes, some containing multiple pills, were tossed into garbage bags. Just one glance inside a bag was enough for me to completely abandon the option of using post-consumer waste as a source of material. I had assumed some sorting would be required, but I had not anticipated it would be on this scale. It took a day to sort the five kilograms of waste by hand. The combined value of the APIs was less than $300. There was no way that this could be profitable or scalable. Nonetheless, I pushed on.

A.4 Scientific Validation

On 10th August 2020, I received a message from the analytical chemist hired for the project. He had completed the first extraction of an API *trimipramine* from an expired medication. He reported that the purity was 98%. After one more round of processing, it was 99.998% pure with no trace elements or pigment. From the perspective of a research scientist, this material was perfectly reusable for non-human R&D, well beyond the typical industry standard of 95%+ (Pollack, 2011, p.). Although there was ample evidence in the scientific literature that this was possible, I was still very excited about this. It was one thing to read about it being possible but quite another thing to do. More importantly, he had achieved the extraction by deploying a unique process that had not previously been used for a similar purpose. This process would become the first intellectual property developed by the company.

Since I was pressured to demonstrate progress, I wanted to share this news with others. Although we had yet to sign a customer or hired staff, this was a step toward developing our non-SAAS equivalent of an MVP. I wrote a press release and shared it with the Communications Manager at Genesis Centre. She made some edits and forwarded it to the communications branch of the local university, who then issued a formal press release to their extensive network of journalists and news outlets. The Telegram newspaper was the first outlet to pick it up, and a follow-up CBC was the biggest hit. Normally our website got ten visits a week. The article drove thousands of hits for three days. Five people emailed and asked if we were publicly traded on TSX or NASDEQ so they could buy shares in the company.

This activity officially satisfied two initial success criteria: technology and intellectual property. The process verified that the target ingredient could be isolated and recovered in a state suitable for reuse. We also completed an initial scan of intellectual property. We confirmed with

an IP lawyer that the process would potentially qualify for a patent, should we pursue it. However, we were encouraged not to patent the process since it would disclose it to others. So, it was later classified as a trade secret.

A.5 Automated Sorting Technology

Based on the unorganised state of the unused medication, it became clear that the medications would have to be sorted before the ingredients could be extracted. It would be hard to isolate the target ingredient with many other compounds. In September 2020, I wrote a proposal to Green Centre Canada for a grant that would provide 75% of the cost of projects to support green chemistry. The proposal included the costs to hire an outside engineering firm to modify an existing mechanical eye and to identify and remove select pills from a moving conveyor belt. The project cost about $20,000 and would take about eight weeks.

The project began in October 2020, and by December, the team had completed proof of concept. However, we no longer required the technology by the time the project was completed. As I will discuss later, sorting individual tablets was no longer necessary since we had moved on to a waste source that did not require sorting.

A.6 Pharmacy Professor

Since there was no local network in the pharmaceutical industry, I began reaching out to industry experts directly. I set up several exciting calls with researchers in India, New Zealand, and the UK, all of whom supported our concept. I agreed that pharmaceutical waste was bad and that reusing it was at least as good as incinerating it.

At this stage, I was feeling conflicted about the project. All the success and encouragement gave me a feeling of cautious optimism. I believed I had come across a novel

solution to a problem becoming more of a priority for the industry. Indeed, all of the informants I had spoken to felt the same. But the fear that I was missing something continually nagged at me. I was aware of my naivety as an industry outsider. Therefore, once I became competent in the high-level operational knowledge of the industry, I never stopped searching for detractors.

A professor of pharmacy from a university met with us on 20 October 2020. He was very adamant that the idea would not work. He reiterated that APIs are made on such a large scale that there is no way recovering them can come close to the per-kilogram price. He gave an example of his mother's cancer pills that he traced back to a facility in India. What retailed at $300 per tablet was made for $.30 per tablet. We would never be able to achieve profitability. He encouraged us to walk away from the project entirely. This was bad news. At the time, I felt a mix of disappointment and relief. I was disappointed because the project would likely come to an end. I also felt relieved that I had finally heard the "truth" from a reliable source. It was valuable advice, and I wish we had obtained it sooner.

As I planned the next step, I thought about how embarrassed I would feel if I shut down the project. All the people that did not believe in me would be right. As I shared the information with others, I received a lot of the same advice: "stick with it," "don't give up," and "you'll figure it out." My appreciation for the support from the ecosystem was now turning to annoyance; I thought to myself, "It's easy for you to say "Stick with it" because you're not the one going through this." I thought most people would just give up and move on by now.

After a day, I put the feedback into a new context. First, the informant was a professor rather than an entrepreneur. While he encouraged us to stop the project, he could not suggest any modifications to the business model to help it work. This did not align with the feedback I was getting from industry experts telling me that a lot of valuable material could be recovered.

Second, what he was saying was true. We would unlikely ever reach the scale required to be competitive with large generic API manufacturers. My view of the viability of the opportunity remained intact. The recovery of valuable APIs was still possible. The only way forward would be to focus on higher-value material. So, in roughly two days, I had gone from shutting down the project to looking for a new, higher-value source of pharmaceutical waste.

A.7 CDL

In October 2020, UnBound was admitted to the Atlantic- Prime stream of Creative Destruction Labs (CDL). I applied in 2019 but was rejected because the project was very early-stage. Many of the mentors were seasoned business veterans, investors, and technology experts, not chemists or pharmaceutical experts, so they primarily focused on the company's viability, profitability, and scalability. The first feedback I received was: “This is just an idea, not a company.” Other mentors commented on the lack of market, defendable intellectual property, and regulatory barriers and asked about team members, competition, and total addressable market. This was the highest level of scrutiny I had ever received. I got to receive it three times. By the end of the meeting, I was drenched in sweat. Thankfully, the meetings were virtual, so I could log off and quickly change my shirt. I received an email from the organizer the following Monday– somehow, I progressed through the first session. The next session was on 25 November 2020. However, I felt that I was on thin ice.

A.8 Investor Feedback

On 18 November 2020, I was picking up the dry cleaning when I spotted a local investor who was also a CDL advisor. I wrote him on LinkedIn, and we met for a beer shortly after. He didn’t waste any time and promptly told me that “recycling grandma's pills” wasn’t exciting or

scalable, that the current model would not work, and that I would almost certainly get cut from CDL in the next round.

Based on the previous conversation with the pharmacy professor, I had already begun researching the possibility of recovering higher-value material. This led me to analyze production waste. Since our biggest challenge was sourcing a homogeneous waste source that did not require sorting, production waste, such as material from off-spec batches, seemed an alternative. I had not practiced or refined the pitch but started anyway. The high-level pitch was: "that the pharmaceutical production process creates 100kg of waste for every 1kg of product, environmental regulations are changing and the industry is looking for solutions".

His response was, "That's very interesting. We would fund a pilot project with a pharmaceutical company if you can get one."

He wrote to me later, saying, "Thanks for reaching out. If you can articulate what you said to me in CDL, I'll support you through the next round". At the next session of CDL, I described how our process could be used to recover material from various phases of pharmaceutical production and how the recovery aligned with regulations and the move toward more sustainable industry practices. This resonated much better with the CDL advisors. I progressed through the rest of the sessions and was one of the seven (out of 30) companies to graduate from the program. The mentorship, guidance, and introductions to multiple pharmaceutical companies would prove incredibly valuable.

Business Model B: Production Waste Recovery

Business Model Summary
Value Proposition: Recover material from production waste for reuse by manufacturers.
Duration: 54 weeks (October 2020- July 2021)
Outbound actions: 594
Scheduled events: 45

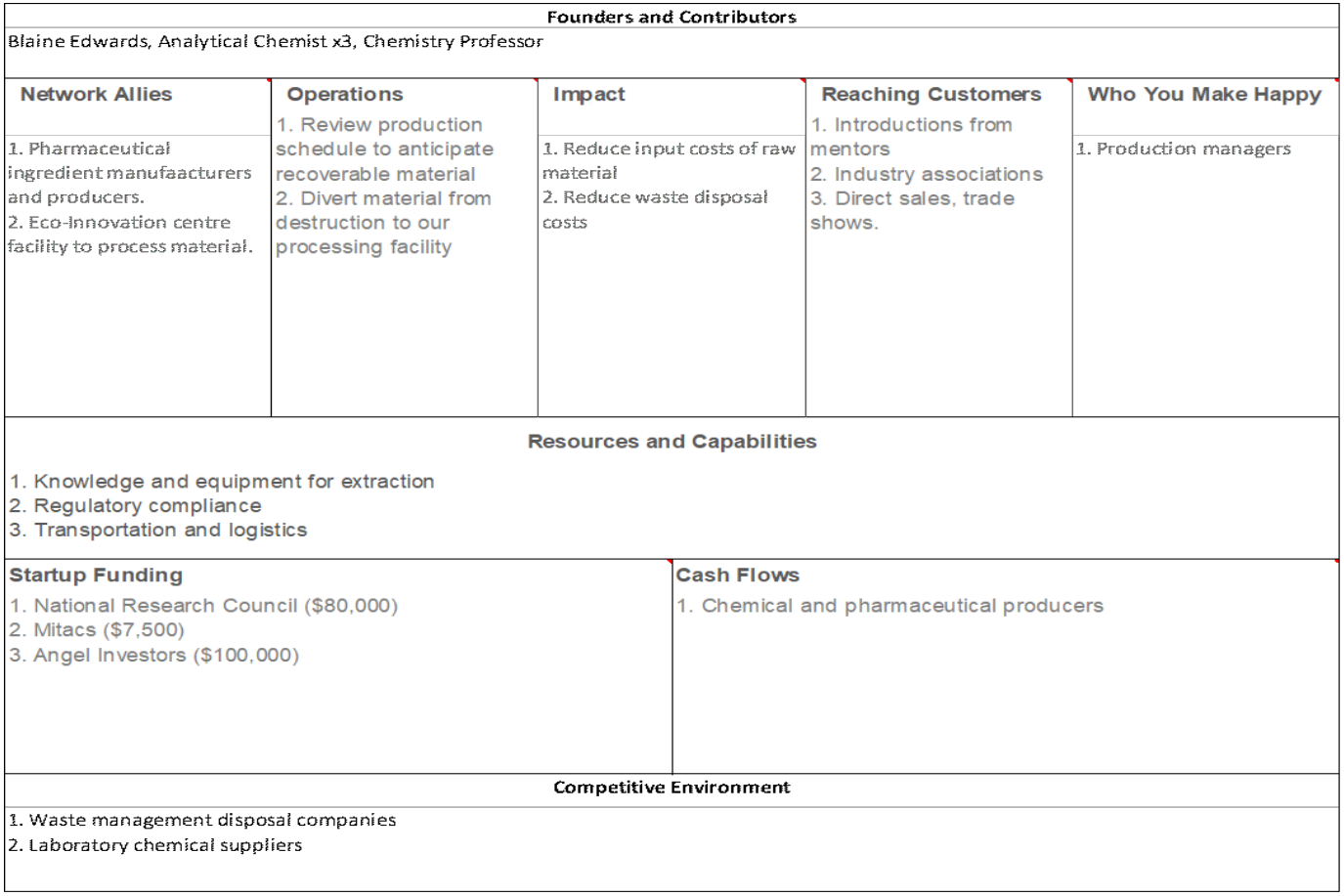

Figure 8: Business Model Canvas B

Business Model B: Impact of Accounts on Success Criteria

No.	Item	Description	V	T	IP	P	S
B.1	Generic Company Alpha: Meeting 1	First interaction with a pharmaceutical company decision-maker.	+	+	/	+	/
B.2	Retired Pharmaceutical Production Manager	Use of informant to verify claims, business model, and proposal objectives.	+	/	/	/	+
B.3	Generic Company Alpha: Meeting 2	Failure to convert pharmaceutical partner to a proof-of-concept study.	+	/	/	-	/
B.4	Entrepreneur in Residence Job	Obtaining a job in the ecosystem extended my ability to evaluate the opportunity and developed my assessment skills.	+	+	+	+	/
B.5	Building Advisory Board	After realizing my limitations, I started recurring a formal board of advisors.	-	/	/	-	-

Figure 9: Account Impact Scoring Business Model B

B.1 Generic Alpha: Meeting 1

CDL advisors made introductions to two pharmaceutical companies to discuss a potential proof-of-concept study on the recovery of production waste. This was precisely the benefit I was hoping to get from CDL. On December 5th, 2020, the analytical chemist I was working with, and I had a Zoom meeting with an executive with Generic 1. This was an introductory call. However, since neither of us was knowledgeable about pharmaceutical production, we also had to conduct some exploration. We did not know what to ask. However, we felt he saw potential in the idea because he was willing to meet with us.

While the discussion was not particularly well structured, it eventually became clear that the company discarded potentially recoverable material when scaling up formulations and running validation batches. This trial and error process used a lot of material, and if part of the material could be recovered, they could reuse it in subsequent production runs. He disclosed that this material could save them $2-3 million annually. He agreed that it was possible to recover the material from a scientific and regulatory perspective.

However, he felt the more significant opportunity was to recover material from the R&D process. He explained it to us. Here, the R&D branch also uses trial and error to fine-tune the synthesis of pharmaceuticals that could be optimized for large-scale production. This process began up to a year before patents expired so their genetic versions could be ready to hit the shelves the day after the patents expired. He believed the low volume and high value (calculated based on the time required for his team to synthesize the correct formulation that worked and did not risk infringing on intellectual property) would be a better business case. Nonetheless, he agreed to pull in team members from the company's formulation and regulatory compliance areas for an initial meeting.

Two follow-up emails were sent in January and February 2021. The second email received the following reply:

"Sorry, Blaine, for the delay,

What you explain [recovering R&D material] makes total sense. I have not connected with the R&D teams (formulation R&D does not report to me), but I do not see a concern for them to move forward on this proposal.

I will connect to them and connect back to you with a proposed molecule

hope that works and best regards."

A meeting was arranged with five Generic A R&D and formulation leadership members for 10 March 2021.

B.2 Retired Pharmaceutical Production Manager

In February 2021, between meetings with Generic A, a contact from CDL introduced a retired pharmaceutical production expert in the Netherlands. This was an excellent opportunity to gather information ahead of further meetings. I treated the meeting like "Production 101" and made sure to get clarification on even the most basic questions. The main takeaway from this meeting was that scaling up production created larger volumes (5-50kg) of homogeneous waste. The product would be destroyed if it was "too off-spec" or if it could not be reformulated or modified to meet the target. Another significant discovery was that he felt that recovery and reuse of the material "should be possible within regulations" and "don't let anyone else tell you otherwise."

This filled us with confidence ahead of our meeting with Alpha. We thought we had a good handle on how the project could create value for the manufacturer.

B.3 Generic Alpha: Meeting 2

On 10 March 2021, I entered the meeting with Generic A armed with what I believed was an improved understanding of their problem. We did a round table of introductions. There was management from various company branches, including regulatory compliance, production, formulation, and R&D.

However, I made a significant error in the meeting. In my slide deck, I presented two potential options for a pilot project, one focused on recovering validation batches material and another focused on recovering high-value R&D material, as the contact had suggested. I started with the validation batch because I assumed it would have a more significant financial impact for them, or my meeting in B.2 led me to believe. I was shortly interrupted by one of the attendees who corrected one of the points on my slide. Contrary to what my contact at Alpha had informed me, Generic Alpha was allowed under Health Canada Regulations to sell the medication they manufactured from validation batches so long as they met requirements. They dedicated a lot of resources to minimise the chances of a failure of a validation batch so there was no waste to recover from that waste stream. This completely derailed the meeting. Another attendee offered other possible opportunities to recover scale-up material and estimated they could save $2 million annually. However, they would require “a study of the impact on operations” and assess “the impact it would have on timelines.” The R&D lead said, “This is a noble effort, and I commend you for that, but I’m not sure of the business case. Science is not the challenge here; the challenge will be regulatory compliance and feasibility of the project”. The meeting closed with comments from the executive: “But going forward, we’ll have to do something in the form

of a formal business proposal, and it's up to you to make the business case, and we can take it from there." I did not have time to discuss the R&D material recovery in the meeting before we ran out of time.

I felt like I had been exposed as a total fraud. The pharmaceutical production process was a highly regulated, complex, and technical process. I could not wrap my head around how I would be able to close the knowledge gap on this since my initial value proposition had been proven false. I did not know where to turn, so I never submitted the proposal, and the opportunity fell apart.

B.4 Entrepreneur in Residence Job

By March 2021, all funding had been exhausted, and I could no longer sustain my full-time exploration of the opportunity. When I began the venture, I promised my spouse that I would always financially contribute to our household. It did not seem fair to rely on her financially while I pursued a venture.

On 17 March 2021, I was offered a full-time position as Entrepreneur in Residence at Bounce Health Innovation. The role involved helping early-stage health and science-based researchers commercialise their technology. I would mentor 15 early-stage entrepreneurs. Fortunately, the director also saw the potential value of what I was working on, so UnBound was brought in as one of the 15 member companies. This allowed me to dedicate a few hours a week to UnBound to continue to explore the opportunity. Although it significantly reduced the volume and frequency of evaluation activity, it did enable me to sharpen my evaluation skills daily. My primary job was to help other early-stage science-based ventures get off the ground. This includes asking questions and assessing the viability of each project. I was essentially evaluating other projects with similar criteria that I was using.

B.5 Building Advisory Board

Needing more direction and insights into the industry, I built a formal board of advisors in May and June 2021. This would help guide the project, lend credibility, and make more introductions to prospects and informants. A chemistry professor at the University was already a de facto advisor so I formalised it with a small equity portion. A local investor was also willing to be a formal advisor but declined any compensation. With weak ties in the industry, I resorted to LinkedIn to find some potential advisors. In the initial phase, I was not picky. I messaged thirty individuals who were recently retired from the pharmaceutical industry. I assume that recently retired people would have the knowledge and time to assist with the project.

Around this time, a fellow entrepreneur and friend gave me sound advice: "Don't half-ass the advisors. Find the absolute highest ranking, the best person on the planet and ask them". It was sound advice.

I held seven meetings with potential advisors and ultimately decided on three:

1. Retired pharmaceutical production expert;
2. Contract Research Organisation (CRO) consultant; and
3. Global expert in pharmaceutical green chemistry.

The third expert was inspiring. The organisation they were with was an industry leader, had extensive industry knowledge, and he had well-established relationships with all the top pharmaceutical companies.

Business Model C: Distributor Recovery

Business Model Summary
Value Proposition: Recover APIs from excess inventory pharmaceuticals for reuse in production.
Duration: 8 weeks (June 2021- August 2021)
Outbound actions: 25
Scheduled events: 4

Founders and Contributors				
Blaine Edwards				
Network Allies 1. Pharmaceutical producers and wholesalers 2. Eco innovation centre to process material 3. Health Canada	**Operations** 1. Take expired, or near expired, medication from warehouses and recover the API or other value ingredients. 2. Re-certify the API and return to manufacturer.	**Impact** 1. Provide material back to manufactuere at lower cost than new material 2. Reduce waste disposal costs	**Reaching Customers** 1. Introductions from mentors 2. Industry associations 3. Direct sales, trade shows.	**Who You Make Happy** 1. Production managers
Resources and Capabilities 1. Knowledge and equipment for extraction 2. Regulatory compliance 3. Transportation and logistics				
Startup Funding 1. National Research Council ($80,000) 2. Mitacs ($7,500) 3. Angel Investors ($100,000)		**Cash Flows** 1. Chemical and pharmaceutical producers		
Competitive Environment 1. Waste management disposal companies 2. Pharmaceutical ingredient manufacturers				

Figure 10: Business Model Canvas C

Business Model C: Impact of Accounts on Success Criteria

No.	Item	Description	V	T	IP	P	S
C.1	Generic Company Bravo	This is an example of how access to new information can bring new opportunities during the evaluation process.	+	/	/	-	-

Figure 11: Account Impact Scoring Business Model C

C.1 Generic Company Bravo

The pharmaceutical production advisor immediately introduced me to another generic drug manufacturer. I contacted the Chief Science Officer (CSO) and scheduled our first Zoom meeting for 4 June 2021. Generic Company Bravo was different from Generic Company Alpha. Bravo did not produce their products and instead outsourced total production (formulation and packaging) to India and then imported the goods into Canada for sale and distribution. Therefore, they did not have any R&D or production waste to recover. Their waste source overstocked inventory in their warehouses, other distributors, and pharmacies. This would lead to exploring the third business model focused on recovering material from distributors.

In our meeting, I ran through a short presentation outlining the vision of recovering APIs and reformulating them into pharmaceuticals. It was well received, and he shared that he had had a similar idea while completing his PhD. “I thought to myself, why must we destroy all of these PAIs [pharmaceutical active ingredients]? However, I chose not to pursue, so here I am”.

He disclosed that the COVID-19 pandemic had left them with $2 million worth of excess inventory of a particular drug. These were finished tablets in the original packaging. They were too close to the expiry date, so they could not be sold. He was interested in having UnBound recover the (relatively) expensive active ingredient and sending it to their facility to reformulate into new tablets. The chain of custody remained intact since the medications had been stored in their secure, temperature-controlled facility.

I thought the meeting went well, so I was disappointed when my follow-up emails and calls went unanswered. Feeling a bit rejected, I sent another email but also cc'd the CEO to quicken a response. Even though I knew it was a bad idea since it would reflect poorly on the CSO and likely result in a “no thanks,” I did it anyway. I wanted to get confirmation so I could

cross it off my list and move on to the next issue. Although my OFB remained high, my SSE was starting to wither. I had been exploring the opportunity for 18 months and had not yet found an industry partner to complete a proof-of-concept project. I received an email on the 19 August 2021. He informed me that they could not proceed with the project. However, it was not from lack of interest. They had done some initial research and disclosed that they did not fully own the rights to the API in their product, and their suppliers did not feel comfortable having a third party recover the API because they "already have a recovery process approved in the DMF by Health Canada".

Although I was disappointed that they would not pursue a pilot project, I was intrigued by the fact that they already had a "recovery process" approved by the national regulator. I had not encountered this before, so it was valuable intelligence. Further correspondence with Health Canada would confirm that when registering a pharmaceutical process, manufacturers could include the criteria, scenario, and technical process for recovering ingredients from the production process in their Drug Master File or DMF. The DMF outlines all the specifications for the production of a pharmaceutical. Producers are required to follow the DMF, and anything that does not meet the specifications cannot be used. Theoretically, the active ingredient section could include the process for recovering API from expired or near-expired medication from pharmacies and distributors that had not been dispensed and that had an intact chain of custody. But, since the DMF is submitted for regulatory approval, the recovery process would have to be fully assessed and verified before approval. Since recovery is not required or usually part of the submission, including it in a DMF might delay the DMF approval. This would not be worth the risk in an industry already plagued with lengthy approval processes.

Business Model D: Pre-Clinical Waste Recovery

Business Model Summary
Value Proposition: Reduce R&D costs by recovering high-value material.
Duration: 16 weeks (July 2021- October 2021)
Outbound actions: 154
Events scheduled: 12

Founders and Contributors				
Blaine Edwards and advisors (CRO advisor, chemistry, regulatory, pharmaceutical green chemistry)				
Network Allies	**Operations**	**Impact**	**Reaching Customers**	**Who You Make Happy**
1. Innovator pharmaceutical companies 2. Generic pharmaceutical companies 3. Contract Research Organisations (CROs) 4. Univerisities	1. Obtain waste material from pre-clinical custom synethsis. 2. Access synthesis route data from Electric Lab Notebook (ELN) 3. Analyse material 4. Recover high value material and return to client	1. Reduce cost of custom synthesis 2. Reduce delays faced by research teams that wait for new material 3. Improve ESG performance	1. LinkedIN 2. Direct sales 3. Network referrals 4. Publications	1. Small molecule researchers 2. Project managers 3. Investors
Resources and Capabilities				
1. Logistics to collect, ship, and return material without damaging it 2. Analyse waste material 3. Recover waste material 4. Access ELN data				
Startup Funding			**Cash Flows**	
1. National Research Council ($80,000) 2. Mitacs ($7,500) 3. Angel Investors ($100,000) 4. Paid pilot ($100,000)			1. Flat fee for material recovery	
Competitive Environment				
1. CROs 2. Internal pressure from clients to maintain status quo				

Figure 12: Business Model Canvas D

Business Model D: Impact of Accounts on Success Criteria

No.	Item	Description	V	T	IP	P	S
D.1	Article and Meeting with Multinational Charlie Chemist	As an industry outsider, I continually sought to learn more about chemistry, pharmaceutical development, and green chemistry. During this process, I uncovered a paper where scientists had successfully recovered an API for research purposes.	+	+	+	+	+
D.2	Multinational Pharmaceutical Company Delta	This event was a pitch meeting with a European multinational pharmaceutical company. It is an example of how improved levels of human capital can help redefine an opportunity and associated business model.	+	/	/	+	+
D.3	Research Proposal & Proof of Concept Results	This was the most significant achievement of the entire start-up process. Completing a proof-of-concept study with a major pharmaceutical company positively impacted most success criteria.	+	+	+	-	+

Figure 13: Account Impact Scoring Business Model D

D.1 Article and Meeting with Multinational Charlie Chemist

Since I was enrolled in a master's program at a University, I had access to journals and periodicals on business, chemistry, and engineering through the university library. I found 20+ articles on the impact of pharmaceutical waste on the environment and processes on how APIs could be recovered from various medications. Having received multiple sources of encouragement to focus on recovering R&D material, I dove deeper into chemical engineering journals.

On May 17, 2021, I discovered a paper written by a research group within Bristol Myers Squibb that was published titled *"*A Process for Active Pharmaceutical Ingredient Recovery from Tablets Using Green Engineering Technology*"* (Hiesh et al., 2017).

I could not believe what I read: It described a scenario where research chemists needed a prohibitively expensive API in order to conduct further pre-clinical research. They were not able to procure the API from suppliers or synthesize it in a timely manner. So, they gathered finished tablets from their production facility, which were unusable due to a minor defect. They then milled, dissolved, and recovered the API from the tablets and used the product for their research. Being so pleased with the "high quality" of the result, they chose to publish a paper on their success. Not only did the paper outline the analytical process they used to recover the API, but more importantly, it indirectly answered two main questions: the material could meet the standards needed to be used in pre-clinical R&D, and more importantly, a business case could be made. This answered the key elements of my OFB feasibility criteria. I emailed the paper's primary author; however, they had since retired. I worked my way down the author list, guessing their emails, and eventually connected with the primary analytical chemist from the project. He was more than happy to meet with us to discuss the process he used.

The meeting was only 30 minutes, so we had to extract as much information as possible. While Ali focused on the chemistry, I was primarily interested in whether this was a repeatable process– could other research groups benefit from recovery? His answer was very straightforward: “Sometimes our research is delayed for 6-7 weeks waiting for material to arrive from the CRO… we’re under serious deadlines… if you can provide what we need, then yes, there’s a need for it”. He couldn’t say if other groups would benefit from the process because he was unfamiliar with what they were working on. However, this single-use case was enough to convince me that there was a larger business case.

D.2 Multinational A

Having failed to convert Generic Company Alpha to a pilot, but now armed with new information from the OPR&D paper, I spent May to June 2021 searching for a new opportunity for small-scale R&D recovery. I had tried small CROs who were contracted to synthesize APIs for pharmaceutical R&D. However since they did not own the IP rights to the material, and the activity would be outside the scope of their agreement with their clients, none of the ones I contacted were comfortable with proceeding without the okay from their pharmaceutical partners.

In June, I began targeting innovative pharmaceutical companies (i.e., top 30 brand name pharmaceutical companies) because they held the IP rights regarding small molecule synthesis. More specifically, I was searching for a contact in a pharmaceutical company that was active in green chemistry, was environmentally conscious, and was involved in small molecule drug discovery. I came across a news release about a 2020 environmental sustainability award given to a pharmaceutical scientist. I found him on LinkedIn and sent a template connection request that I had already sent to 30 other scientists:

"Hi _____,

I'm with a student startup that's been researching methods to rapidly recovery pharma production waste (R&D, formulation, pilot batch material, etc). We're focusing on small molecules.

I'd love to connect to learn more about your role and discuss our research to date.

Thanks,

Blaine"

To my surprise, I heard back within a couple of hours. He said that it sounded interesting and requested a short proposal outlining our request that he could share with a colleague. The next day, he introduced me to his colleague who worked in the small molecule research division. He said that my request was timely because "we are facing delays due to supply chain issues caused by COVID-19".

The meeting on 1 July 2021 was attended by six people from different positions in the company, including legal, regulatory compliance, research, and environmental sustainability. I ran through a presentation that included a review of the outcome of our recovery research, testimonials from other R&D scientists about how material recovery could help improve research timelines, and how the material was suitable for preclinical research according to industry standards.

Based on the information I had received from the multinational scientist, I gave an example of an API that took over 100 hours to synthesize and cost $100,000 per gram based on material and labor inputs. Even if recovery was just 10-15% of the volume, that could be enough to continue research while they waited for more virgin material. The recovery process could also reduce the total amount of synthesis activity in the company, which would help support its GHG reduction targets. When under strict deadlines, it's not uncommon for chemists to use processes that result in small yields and generate a lot of side reactions, by-products, and waste that are

discarded. The meeting ended with little discussion after the presentation. They thanked me for my time and indicated they would follow up with the next steps should they wish to continue.

Just two days later, I received an email introducing me to "my main contact" with the company that "will guide you through the pilot process." My contact with the company quickly became a real champion. He was environmentally focused, understood that the recovery of small molecules was achievable, and was willing to promote the project from within the company. We met four times over six weeks and exchanged ideas on recruiting a research team to the project.

D.3 Research Proposal & Results

On 11 September 2021, my contact requested a formal research proposal that he could present at a quarterly meeting of research group leads that was scheduled in October. This would be the best opportunity to recruit a research group to complete a proof-of-concept study.

The resulting proposal was eight pages and outlined:

- The purpose and objective;
- Our research to date and how high-value material can be recovered from custom synthesis waste (side reactions, big projects, and unsuccessful reactions).
- The potential impact on research timelines, cost reduction, and GHG emissions.
- Our team and advisors (which now included green chemistry experts from the pharmaceutical industry).
- Instructions on where and how to look for higher-value material from custom synthesis.

The meeting was scheduled for 11 October 2021. The following day, we connected online, and he said that he had delivered a short presentation to the small and large molecule research project managers. Unfortunately, neither of the groups seemed interested in taking on an

additional project. He said that “the conversation immediately went to validity and GMP” (good manufacturing practices/regulatory issues). On 27 October, one week later, he messaged me on LinkedIn and asked if I was free for a quick call. He said he had an update. Given our previous conversation's lack of enthusiasm for the project, I assumed he had received a formal rejection. We scheduled a call for that Friday, two days later. The meeting started with the same small talk, but I could tell he had good news to share because he was smiling more than usual. He finally shared that a group of small molecule researchers had heard about our proposal and took it upon themselves to try a small study. During downtime, a few medicinal chemists followed our instructions and searched for the waste material from custom synthesis research. “They did a quick calculation of envelope maths, and they estimated that the few grams of material they reviewed was valued at $4 million”. He further informed me that this was waste from just one step (of which there were usually a minimum of seven and up to fifteen) and from one research project. At the time, the small molecule group was researching hundreds of other compounds. Due to time constraints, they had not actively recovered the material for reuse. Nonetheless, this validated our claim that bi-product waste existed and was valuable.

“The chances of doing a larger project with us went from 0% to now a 50/50,” he said. But, there was another consideration. The company had an annual research budget of several *billion* dollars. In the grand scheme of things, $4 million made up a small fraction of that budget, and scaling it up would require a significant investment into ironing out new standards and internal logistics. In sum, it wasn’t worth it. So, in order for them to sign on, the benefits of the project would have to go beyond just the direct financial benefit of material recovery. The company did not think in terms of “costs”, they focused on outcomes. Therefore, it would have to positively impact the timeline or outcomes of small molecule research.

By the end of the meeting I was in a daze of disbelief. Once I closed the laptop, I looked up to the ceiling and sighed, "*shit*." I was pleased; perhaps a part of me felt a bit smug, but I was overcome with a feeling of dread. I felt like a dog that had just caught the car. At that moment I realised that I had spent so much time and energy on finding a proof-of-concept partner that I had neglected to plan for once I found them. I was without the right team members, inventors, or mentorship. I had no idea what to do next.

Business Model E: Negative Reaction Data, Machine Learning, and Computer-Assisted Synthesis Planning (CASP)

Business Model Summary

Value Proposition: A financially self-sufficient way to characterise and digitize negative reaction data and improve research timelines.

Duration: 15 weeks (October 2021- February 2022)

Outbound actions: 78

Scheduled events: 8

Founders and Contributors				
Blaine Edwards and THREE advisors (CRO advisor, chemistry, pharmaceutical green chemistry)				
Network Allies 1. Innovator pharmaceutical companies 2. Generic pharmaceutical companies 3. Contract Research Organisations (CROs) 4. Univerisities 5. Chemical synthesis machine learning companies and researchers.	**Operations** 1. Obtain waste material from pre-clinical custom synethsis. 2. Access synthesis route data from Electric Lab Notebook (ELN) 3. Analyse material 4. Digitise side reactions and bi products 5. Recover high value material and return to client	**Impact** 1. Make digitisation of chemical reactions more feasibile 2. Improve speed of achieving pre-clinical outcomes 3. Support accuracy of ML models with negative data	**Reaching Customers** 1. Direct sales 2. Publications	**Who You Make Happy** 1. Medicinal chemists 2. Project managers 3. Investors 4. Computationl chemists
Resources and Capabilities 1. Logistics to collect, ship, and return material without damaging it 2. Analyse waste material 3. Recover waste material 4. Access ELN data 5. Digitisation of physical material into ML readable format				
Startup Funding 1. National Research Council ($250,000) 2. Angel Investors ($100,000) 3. Paid pilot ($100,000)		**Cash Flows** 1. Paid pilot ($100,000) 2. Pay-to-play fee for access to database		
Competitive Environment 1. CROs 2. Internal pressure from clients to maintain status quo 3. Computer Assisted Synthesis Planning companies				

Figure 14: Business Model Canvas E

Business Model E: Impact of Accounts on Success Criteria

No.	Item	Description	V	T	IP	P	S
E.1	Feedback from Advisors	The feedback from advisors on the successful proof-of-concept project demonstrates that advisors are helpful in providing different courses of action. However, the best course of action may not be one of the suggested paths.	+	/	/	+	/
E.2	Research & Literature Review	This is an extreme example of my motivation, focus, and ability to take on research into unknown matters.	+	+	+	/	/
E.3	Negative Reaction Expert	This was a breakthrough moment where the value of waste material as “negative reactions” was discovered.	+	+	+	+	+
E.4	Machine Learning Expert at Multinational A	During this meeting with an ML expert, I learned about different data sources for the pharmaceutical industry.	+	/	+	/	+

Figure 15 Account Impact Scoring Business Model E

E.1 Advisors

Following the meeting with my contact from Multinational Delta, I immediately contacted my group of advisors to share the results of the unofficial pilot. I explained the significance in terms of the proof-of-concept that it provided. The three advisors offer a range of advice on the next step.

- Investor: Suggested that we get them to agree to a formal pilot project so the full impact of the results could be understood to make the business case. Also, include that a white paper be published on the outcome.
- CRO Advisor: Was pleased to hear the outcome but provided no suggestion or guidance on the next steps.
- Analytic Chemist: Suggested that we needed to conduct more research on the extraction process and finalise the patent on the recovery process before we move to a pilot.
- Pharmaceutical Green Chemistry Expert: In order to prove value beyond the material recovery, he recommended that we investigate the impact the data could have on machine learning models. He recommends looking into the work of Klavs Jensen's group at Massachusetts Institute of Technology (MIT).

The feedback regarding ML models was the most interesting. It had not come up in previous discussions with advisors or mentors because our conversations had been limited to the business case of recovering material. It also provided a possible additional benefit that could be presented to Multinational A that went beyond the financial impact of recovering material.

E.2 Research & Literature Review

In October 2021, I began to research the role of machine learning in small-molecule drug discovery. Using periodical search tools, I found the most referenced articles on the matter that Klavs Jensen authored. The starting place was an article from 1985 entitled *Computer-assisted Analysis in organic synthesis* (Corey et al., 1985). I subsequently reviewed the references and then read them. This process was repeated until I had reviewed 125 papers on the subjects of:

- Machine learning in drug discovery;
- Chemical synthesis, including forward and retrosynthesis;
- Data collection methods in lab-based pre-clinical research; and
- Implications of data quality on machine learning.

While I did not understand many detailed discussions regarding chemistry, cheminformatics, or machine learning, reviewing the articles chronologically began to tell a story. Small molecule drug discovery still follows the Design, Make, Test, Analyze (DMTA) process. The job of "Making" small molecules falls to medicinal chemists, who are tasked with making the first physical samples of potential drugs for subsequent Testing and Analysis.

Medicinal chemistry has been compared to cooking. Medicinal chemists (the cooks) design synthesis pathways (recipes) based on the success of previous recipes and their own hunches in order to achieve a successful synthesis (the cake). However, they are often the first cooks in history to ever attempt a given recipe, so they are often in the dark. With over 250,000 possible starting ingredients and each recipe requiring at least seven steps that could include different temperatures, pressure, and duration, there are trillions of possible combinations. It is estimated that there are 10^60 possible druglike small molecules; to date, we have discovered

10^8 (Stockwell, 2011). The biggest challenge for medicinal chemists is designing a recipe that will work– because, most of the time, they will not (Wess et al., 2001). Small molecule drug discovery is essentially a chemistry-themed guessing game, and machine learning can help chemists design successful recipes by analyzing existing recipes and recommending a combination that may be successful (Corey, 1985).

Many papers regarding ML for chemical synthesis reference the unavailability and low quality of machine-readable data as a barrier to realising the full potential of machine learning for chemical synthesis (Coley et al., 2018).

E.3 Machine Learning Expert with Multinational Delta

Having learned about the importance and lack of quality data in the industry, I set about looking to find verification. I searched online, trying to find someone with the right background. I sent many emails that received no reply. One MIT alumnus that was part of Jensen's group shared a common connection on Linkedin. I messaged our shared connect and explained what I was researching, and he agreed to make an email introduction. The meeting was set for 12 December 2021.

This informant provided insights on data quality issues but not on the medicinal chemistry procedures. "When I joined the company, I was very excited, but what I found was a huge amount of data that was practically useless. The lab notes are unstructured… an experiment from 1989 had a yield of 0. Was that an issue with the experiment, or did somebody drop a flask? There's no way to tell". He also did not seem overly impressed with our proof-of-concept study recovering $4 million worth of material. His goal was to progress and improve research outcomes, not save money, which aligned with other feedback I had received.

Ultimately, he was unsure about the potential value of the data since we could not provide him with any examples. But had confirmed that the data quality was important and that they lacked the quality data he needed. Since I had no results to share, he said, "Let me know when you find something demonstrable, and then we can talk again."

E.4 Dark Reaction Expert

One particular paper stood out: *Machine-learning-assisted materials discovery using failed experiments* (Raccuglia et al., 2016). The authors had proven that datasets that only contain successful material chemical reactions are less useful than datasets that contain successful and unsuccessful (known as negative reactions) chemical reactions. Essentially, from a machine learning perspective, knowing what reactions *do not* work is just as valuable as knowing what reactions *do* work. A subsequent paper claimed that negative reactions "would present tremendous opportunities for future research" for machine learning small molecule drug discovery (Cooley et al., 2018, p. 1286). Computer programs and chemists alike are destined to waste time reperforming chemical reactions that will never work without knowing about failed reactions. Since scientists are less likely to share the results of "failed experiments," the authors dubbed these reactions "dark reactions" (Raccuglia et al., 2016, p. 73).

It then dawned on me ***that chemical synthesis waste could be the same thing as negative reactions*.** What chemists were disposing of was, in essence, material from failed reactions or the left-over material from their activity that included side reactions, bi-products, and other unanticipated or unrequired chemical actions.

One of the principal authors was now a chemistry professor and was happy to arrange a call with me. With a basic understanding of some of the issues regarding machine learning and

small molecule development, I reached out to the authors of the paper to verify three assumptions:

1. That scientists do not regularly analyze waste (now called side reactions or bi-products) of chemical reactions.
2. That characterising the side reactions was too time consuming and/or cost prohibitive for researchers.
3. The negative reaction data could be used to create more accurate and reliable machine-learning models for chemical synthesis.

Since he was in academia and not in industry, he could not comment on industry practices regarding side reactions. However, as a chemist and machine learning expert in chemical synthesis, he was sure of the benefits that negative reaction data could bring to ML. Introducing negative data can remove synthesis routes (recipes) from the options if it contained a reaction that was proven not to work, “there are just too many routes available… we need to be able to shut some of the doors early”.

Final Business Model

Success Criteria	Criteria Description	At the Time of Founding	At the End of the Evaluation
Viability	The project was achievable in terms of regulations, waste availability, and human resources.	At this stage, I had anecdotal evidence that access to material, human resources, and laboratory facilities was possible. The regulatory component was not clear.	The project identified a pre-clinical custom synthesis as a high-value waste source that could be recovered in adequate volume and meet regulations.
Technology	A process that could successfully recover targeted ingredients from a waste source.	I was satisfied that the necessary scientific process was readily available.	The recovery of material and necessary characterisation and digitization of material was achievable and within means.
Intellectual Property:	Novel technology or processes that would give the company an element of exclusivity and competitive advantage.	This was not clear at this stage. However, I was comforted that a novel process could not be developed through literature alone and that time in the lab was necessary.	The process we developed was novel. Adding high-value dataset generation was an additional feature not intended at the outset but provided an additional layer of protection.
Profitability	The material could be recovered and sold for less cost than it could be developed through traditional means.	This was also unknown. However, the anecdotal accounts about the high value of research chemicals did provide some evidence that it was possible. Similarly, my research into the gram-level value of APIs made me believe this was possible.	The proof of concept project with the large multinational provided sufficient evidence that the material was of higher value than the cost to recover it.
Scalability	The solution solved a problem faced by multiple organisations in the marketplace and could be addressed with a non-linear investment.	This was also not known. But, initial research into the research chemical market showed that it was possible.	The amount of effort behind ML for chemical synthesis and the ongoing strength of small molecule discovery represented a large and growing market that could be captured with a non-linear investment. Generating a high-value dataset added an advanced technology component that could improve the high-value and scalable nature of the business.

Figure 16: Success Criteria at the End of the Process

Value Proposition

BECAUSE;

> Negative reaction data is missing if ML will unlock the productivity of small molecule chemical synthesis, BUT negative data is too expensive to collect.

AND

> The side reactions, bi-products, and other material that represents negative reactions are full of high-value chemical intermediates that can be recovered and reused. However, it does not have enough value to act.

THEREFORE

> Negative reaction datasets can be self-sufficiently generated during the characterization and recovery of high-value chemical intermediates from chemical synthesis's bi-products and side reactions.

Decision to Join Another Start-up

During my research, I came across several Computer-Assisted Synthesis Planning (CASP) software products offered by companies worldwide. In 2021, there were also at least five companies in the start-up phase that were bringing new versions of technology to market. I began monitoring their weekly online activity: reading social media posts, noting staff level changes, reading press releases, etc.

In January 2022, one of them posted a job ad on LinkedIn looking for a Business Development Manager. While I had crafted a good value proposition and was in the early stages of fundraising, I was missing the team and technical know-how to attract investment. I could coordinate research and develop proposals; however, assembling the resources needed for

Business Model E on my own seemed beyond my capabilities. Additionally, I had depleted my funding, and most of the early momentum was lost. I was also starting to experience burnout as I worked full-time but continued UnBound in my spare time. It seemed more attractive to join a company with that expertise in place and supplement it with my knowledge.

I crafted a cover letter and resume highlighting my background in entrepreneurship and research into pharmaceutical waste recovery and custom synthesis. I was contacted for an interview, during which I outlined my entrepreneurial experience to date, my understanding of the business case of how ML can improve chemical synthesis, and how I would approach creating high-value partnerships, including being able to build on the relationships I had already developed with Multinational Delta.

I received the offer to join the company on 5 February 2022, six years from inception, four years from part-time exploration, and two years from when I began working on the project full-time. As part of the agreement, I had to suspend all activity of UnBound Chemicals Inc.

Chapter 5: Analysis

In this section, I will present the results of the data analysis, emergent themes, and the impact on the evolution of entrepreneurial opportunities and the development of business models. The results are presented in the same order that the analysis was conducted: business model design, the impact of events on opportunity confidence of opportunity and business models, and thematic coding. The analysis includes business model development of the first business model, and then five rounds of business model innovation as the business model was changed based on feedback.

Business Model Innovation Summary

Business Model	Date Range	Activity	Market	Understanding of Opportunity	Why the Change Was Made	How the Change Was Made
A(i): Getting Started	April 2016-April 2019	1. Collect unused medication from pharmacies 2. Extract ingredients and sell them to someone.	University researchers	Unused medications are discarded when the ingredients could be recycled.	There was a lot of unused medication, and the ingredients were recoverable. Some of the ingredients were valuable.	1. Learning from publicly available source 2. Attending start-up training programs
A: Post-Consumer Waste Recovery	April 2019-October 2021	1. Learn what research chemicals were needed by research groups, 2. Find unused medication that contained the ingredients, 3. Obtain the material, extract the ingredients, and sell them to researchers.	University researchers that need research chemicals.	Some research chemicals are prohibitively expensive for researchers.	1. Learned that the volume of material required for research is very small 2. Post-consumer pharmaceutical waste is not organized (-S, -P). 3. Post-consumer waste does not contain the research chemicals needed by researchers (-V)	1. Find a new target market: Move up the supply chain from post–consumer waste to production. 2. Design new operations for large-scale recovery. 3. Develop new capabilities: Understand pharmaceutical production regulations, operations, and product margins.
B: Production Waste Recovery	October 2020-July 2021	Recover high-value material from the production process and resell to manufacturers.	Pharmaceutical production companies and facilities.	Scaling up production and validation runs creates a high volume of high-value waste that could be recovered.	1. Learned that material from validation runs can already be used, so no waste is created. 2. Firms try to minimise waste.	1. Find a new target market: Move down the supply chain from production to distribution. 2. Develop new capabilities: Understand distribution networks, inventory control, and IP licensing agreements.
C: Distributor Waste Recovery	June 2021-August 2021	Recover API from unsold tablets and resell to producer to use in new production runs.	Distributors, wholesalers, and retailers	The unsellable inventory contains high-value material that manufacturing could recover and reuse.	The distributors did not hold the IP rights to modify the tablets.	1. Find a new target market: Move up the supply chain from distribution to R&D. 2. Develop new capabilities: role of custom synthesis in pre-clinical R&D
D: Pre-clinical Waste Recovery	July 2021-October 2021	Recover high-value material from bi-products and side reactions of small molecule chemical synthesis during pre-clinical research.	Innovator pharmaceutical companies contract research organizations to conduct chemical synthesis.	Chemical intermediates can be recovered and reused to save money.	Innovator pharmaceutical companies have large research budgets and are not motivated by saving money. They are motivated by improving research timelines.	1. Create new impact by improving research outcomes by recovering chemical intermediate recovery and data for ML. 2. Design new operations: Characterisation and digitization of chemical material during recovery. 3. New Capabilities: Data curation, cheminformatics.
E: R&D Waste Recovery and Negative Reaction Data Generation	October 2021-February 2022	Recover high-value material from chemical synthesis and digitize it to help improve machine learning models.	Companies that use machine learning for chemical synthesis (innovator pharmaceutical, chemical data companies, start-ups, and CROs).	The unavailability of negative data limits the utility of machine learning for chemical synthesis.	This business model is still undergoing innovation.	This business model is still undergoing innovation.

Figure 17: Business Model Summary

Analysis of the Impact of Accounts on Success Criteria

As discussed in the methodology section, each account's impact on the business model was rated by its impact on success criteria. The criteria included viability (V), technology (T), intellectual property (IP), profitability (P), and scalability (S).

Business Model A

No.	Item	Description	Success Criteria				
			V	T	IP	P	S
A.1	Chemistry Research Project	A trusted source of knowledge who was willing to be an ally to provide insight into the unknown provided an increased level of confidence.	+	+	/	+	/
A.2	Startup Ecosystem	The start-up ecosystem provided me with training, encouragement, and a low-risk playground in which to develop new skills.	+	/	/	+	+
A.3	Pharmacy Agreed to Share Material	The first instance of successfully recruiting a third party to support the project increased.	+	/	/	+	+
A.4	Scientific Validation	Completion of science research experiment that resulted in the validation of our extraction process.	+	+	+	+	/
A.5	Automated Sorting Machine	This is an example of what happens when resources are dedicated to business models that have not been fully evaluated.	/	/	+	+	-
A.6	Meeting with Pharmacy Professor	Received candid and negative feedback from a reliable source about the unfeasibility of the opportunity.	-	/	/	-	-
A.7	CDL	Impact of enrollment in a technology-focused mentorship program.	/	/	/	+	+
A.8	Investor Feedback	Guidance from investors.	-	/	/	-	-

Figure 18: Business Model A Impact Analysis

Of the eight accounts reviewed for Business Model A, only three contained negative feedback (A.5, A.6, and A.8). The remainder of the accounts were positive or neutral. The negative account of A.5- the Automated Sorting Machine only negatively impacted scalability (S). This was because post-consumer pharmaceutical was too mixed together to bring the solution to scale. However, other components were not impacted (V, T, IP, P), so this account alone did not result in a business model change. Accounts A.6 and A.8 had negative impacts on V, P, and S. This negative feedback was believed to be accurate and came from trusted sources and, therefore, resulted in the first business model innovation.

Business Model B

No.	Item	Description	V	T	IP	P	S
B.1	Generic Company Alpha: Meeting 1	First interaction with a pharmaceutical company decision-maker.	+	+	/	+	/
B.2	Retired Pharmaceutical Production Manager	Use of informant to verify claims, business model, and proposal objectives.	+	/	/	/	+
B.3	Generic Company Alpha: Meeting 2	Failure to convert pharmaceutical partner to a proof-of-concept study. Production waste is not a viable source.	-	/	/	-	/

Figure 19: Business Model B Impact Analysis

Of the three accounts listed for Business Model B, only B.3 contained negative feedback. B.3 was the account that led to the abandonment of Business Model B due to the direct feedback from potential customers. It, too, includes negative feedback for V and P, while the others remained neutral or positive.

Business Model C

No.	Item	Description	V	T	IP	P	S
C.1	Generic Company Bravo	This is an example of how access to new information can bring about new opportunities during the evaluation process.	-	/	/	-	-

Figure 20: Business Model C Impact Analysis

Business Model C is a unique case because it only has one account associated with it. However, it includes negative feedback for V, P, and S. This was because distributors did not have the IP rights that allowed them to modify the tablets. This meant that recovery was not viable, profitable, or scalable. The other factors remained neutral.

Business Model D

No.	Item	Description	V	T	IP	P	S
D.1	Article and Meeting with Multinational Charlie Chemist	As an industry outsider, I was continually looking to learn more about chemistry, pharmaceutical development, and green chemistry. During this process, I uncovered a paper where scientists had successfully recovered an API for research purposes.	+	+	+	+	+
D.2	Multinational Pharmaceutical Company Delta	This event was a pitch meeting with a European multinational pharmaceutical company. It is an example of how improved levels of human capital can help redefine an opportunity and associated business model.	+	/	/	+	+
D.3	Research Proposal & Proof of Concept Results	This was the most significant achievement of the entire start-up process. The successful completion of a proof-of-concept study with a major pharmaceutical company confirmed all success criteria.	+	+	+	-	-

Figure 21: Business Model D Impact Analysis

Business Model D received mostly positive feedback. The value proposition was becoming clearer, and we had completed a successful pilot project. However, the only negative feedback impacts were P and S because it was learned that pharmaceutical companies would not use a recovery service on the basis that it saved money alone. They were more interested in improving research outcomes than saving money on R&D. If customers did not use the company's offering, then the company could not be profitable. Although there was positive feedback on all other criteria, the negative impact on P resulted in still more business model innovation. It should be noted that this is a viable business model that, by itself, generates profit. However, in the context of my criteria, it was important that the business model be profitable AND scalable.

Business Model E

No.	Item	Description	V	T	IP	P	S
E.1	Feedback from Advisors	The feedback from advisors on the successful proof-of-concept project demonstrates that advisors are helpful in providing different courses of action. However, the best course of action may not be one of the suggested paths.	+	/	/	+	/
E.2	Research & Literature Review	This is an extreme example of my own motivation, focus, and ability to take on research into unknown matters.	+	+	+	/	/
E.3	Negative Reaction Expert	This was a breakthrough moment where the value of waste material as “negative reactions” was discovered.	+	+	+	+	+
E.4	Machine Learning Expert at Multinational A	During this meeting with an ML expert, I learned about different sources of data for the pharmaceutical industry.	+	+	+	+	+

Figure 22: Business Model E Impact Analysis

Business Model E had an entirely positive or neutral impact on the criteria. All accounts had either a positive or neutral impact, and there were no negative impacts. This business model was (and remains) the one being executed and was not changed.

Why Business Models Are Changed?

Based on the above analysis, it seems the most influential factor for why business models are changed is P, profitability. Negative impact on P was the only criterion resulting in a change in all five Business Models. Even in cases where other criteria were negative, such as A.5 (S), it alone was not enough to cause a business model change.

Viability (V) was also a strong indicator of business model innovation. It was present in three of the five BMIs. However, in D.3, even though there was a positive impact on V, the business model was changed because of the negative impact on P. So, in this case, profitability was a stronger criterion than viability.

The data does not provide any insight into the importance of intellectual property or scalability. Many of the IP impacts were neutral, and S was usually accompanied by a negative V or P.

It should be noted that no business model had a negative impact on technology (T). It was either an unknown (A(i)) or a constant once it was established in A. Therefore, the role that technology plays in business model innovation is not evident in the data. However, as the founder, I can say with absolute certainty that the start-up would have been abandoned if the technology was no possible or if it could not be applied to the business model.

Overall, there are more positive and less neutral and negative impacts as the business models progress. There were also fewer meetings since my network of advisors could arrange

better and more recent introductions. If we put aside selection bias, this demonstrates an improved ability a acquiring new information, including who to contact, and what to include in communication in order to get them to agree to meet with me.

So, why are the business models of start-ups changed? We can say that business models are changed because founders *believe* that the business model is not, or cannot be, profitable OR that there is a more profitable and scalable option within reach.

Analysis of Changes in Components of Business Model Canvas

Business model innovation is the "designed, novel, non-trivial changes to key elements of a firm's business model and/or the architecture linking these elements" (Foss and Saebi, 2017, p. 210). To analyse how business models are changed, we will review the changes that were made in the components of each business model canvases

Business Model	Network Allies	Operations	Impact	Market/WYMH	Resources and Capabilities	How the Change Was Made
A(i): Getting Started	University start-up programming	Collect under medication from the public and resell ingredients to the industry.	Reduce mediation in the environment	Students and university researchers	Pitching and gaining awareness.	This was the first model, so it was developed rather than changed. Development included: 1. Developing network allies through introductions. 2. Obtaining free resources. 3. Learning what was needed through training.
A: Post - Consumer Waste Recovery	Pharmacies and hospitals	• Learn what research chemicals were needed by research groups, • Find unused medication that contained the ingredients, • Obtain the material, extract the ingredients, and sell them to researchers.	Provide research chemicals that are prohibitively expensive for researchers.	University researchers that need research chemicals.	• Sort medication • Extract the target ingredient	1. Increased collection of feedback (ex., Started cold emailing, asking for intros, etc.) 2. Obtaining technical capabilities by hiring chemists or expanding the network for free advice 3. Public funding
B: Production Waste Recovery	Eco-innovation center to recover material.	Recover high-value material from the production process and resell to manufacturers.	Create less waste from scaling-up production and validation runs that create a high volume of high-value waste that could be recovered.	Pharmaceutical production companies and facilities.	• Extract the target ingredient from a large homogeneous waste source.	1. Find a new target market: Move up the supply chain from post–consumer waste to production. 2. Design new operations for large-scale recovery. 3. Develop new capabilities: Understand pharmaceutical production regulations, operations, and product margins.
C: Distributor Waste Recovery	Eco-innovation center to recover material.	Recover API from unsold tablets and resell to producer to use in new production runs.	Salvage unsellable inventory that contains high-value material that could be recovered and reused in manufacturing.	Distributors, wholesalers, and retailers	• Remove medication from packaging • Extract the target ingredient	1. Find a new target market: Move down the supply chain from production to distribution. 2. Develop new capabilities: Understand distribution networks, inventory control, and IP licensing agreements.
D: Pre-clinical Waste Recovery	Synthetic Chemist Advisors	Recover high-value material from bi-products and side reactions of small molecule chemical synthesis during pre-clinical research.	Chemical intermediates can be recovered and reused to save money.	Innovator pharmaceutical companies contract research organisations to conduct chemical synthesis.	• Extract the target ingredient	1. Find a new target market: Move up the supply chain from distribution to R&D. 2. Develop new capabilities: role of custom synthesis in pre-clinical R&D
E: R&D Waste Recovery and Negative Reaction Data Generation	Machine learning experts	Recover high-value material from chemical synthesis and digitize it to help improve machine learning models.	Create a source of negative reaction data to improve the utility of machine learning for chemical synthesis and speed up research.	Companies that use machine learning for chemical synthesis (innovator pharmaceutical, chemical data companies, start-ups, and CROs).	• Extract the target ingredient • Characterise and digitise material into a machine-readable format.	1. Create new impact by improving research outcomes by recovering chemical intermediate recovery and data for ML. 2. Design new operations: Characterisation and digitization of chemical material during recovery. 3. New Capabilities: Cheminformatics, computational chemistry.

Figure 23: Business Model Component Modification

How Business Models Are Changed?

While going from one business model to another, some components changed dramatically, while others saw small changes or were not changed. Changes to the customer segments (target market/Who You Make Happy (WYMH)) were the most common and took place in all five business model innovations. The market segments were those that created pharmaceutical waste and/or could benefit from reclaimed material. The target market traveled down the supply chain, starting with post-consumer all the way to pre-clinical R&D. Ironically, it began and ended with small volume/high-value chemical synthesis research material after focusing on larger scale product level recovery in B and C. Since the customer location, volume, and value of waste differed for each business model, the operations and network allies' components changed to reflect the operations necessary for that market. For example, "Eco-innovation centre to recover material" was required in B and C to support larger scale recovery, and "Synthetic Chemist Advisors" were required in D. Network Allies and Operations were changed as a result of changes to customer segments but not visa versa.

The impact component changed during each business model. The early impact (A(i)) was purely environmental and focused on reducing the impact of unused medications on the environment. That changed because environmental impact alone was insufficient to convert a prospective customer into a pilot project. The core impact was cost savings for researchers in A, B, C, and D. In model E; it changes to "improve research timelines and outcomes". In this case, the technology did not change, but it was discovered in D.1 that recovery could be used to save time, not just money, an important consideration for pharmaceutical research. Similarly, the customer segments also started and finished with individual chemists after focusing on other downstream stakeholders such as producers, suppliers, and distributors. An important distinction

between them was that the first segment was public university researchers with limited budgets, while the final was private pharmaceutical researchers with large budgets and tighter timelines.

In the initial model (A(i)), no capabilities or resources of any value were listed. The capability of "extract target ingredient" was present in each subsequent business model once it was developed. While there were additions to capabilities, such as removing packaging in C and digitise material in E, the extraction remained in all five. Other capabilities were brought in to supplement the extraction technology and help it fit the customer use case. For example, researching and learning about production regulations (B and C) and machine learning (E) were developed to support customer adoption.

Finally, the level and detail between Business Model A(i)/A and Business Model E are noteworthy. The components in BMA(i) and A were vague, broad, unfocused, unnecessary, or unrelated to the impact and were overly complicated. For example, Another example is the capabilities, where no technical capabilities existed in A(i), and only "scientific know-how" was listed in A. However, while the components were vague, they successfully established the boundaries of the start-up and were built around the assumption that a novel recovery process was possible.

It should be noted that the components of "Start-up Funding" and "Cash Flows" were not included in the analysis because no money was spent. After exhausting the seed money on Business Model A, the subsequent business model innovations were completed with no financial capital investments other than time. After developing Business Model E, I decided to join another similar start-up rather than raise capital.

So, how do start-ups change their business models? The data supports that start-ups change their business model by discovering new markets or customer use cases and then arranging the resources, capabilities, network allies, and operations necessary to achieve the desired impact. The continued presence of core technology (extract target ingredient) tells us that business models can be rebuilt around existing capabilities and can be supplemented by the introduction of others. There can also be multiple business models under assessment simultaneously until the most valuable and attainable becomes clear. The ability to retain information and make unexpected connections is vital, as was the case in (E.4) when the term "waste" was exchanged for "negative reaction." From a theoretical perspective, this activity supports the case that strategic entrepreneurship, not RBV, can be used as a theoretical grounding for business model innovation (Schneider & Spieth, 2013).

The Role of Human Capital

The most dominant theme emerging from the data was human capital development, both investments and outcomes. The investments in human capital included returning to post-secondary education (1.1), enrolling in start-up programs (1.4, A.2, A.7, B.4), building a network of advisors (A.1, A.8, B.2, B.5, E.1), researching new topics (1.1, A.1, B.1, C.1, D.1, E.2, E.3, E.4), hiring when necessary (A.2)), and the aggregate of all the activity led to human capital outcomes. These human capital outcomes included knowledge such as pharmaceutical regulations (B.3, C.1, D.1), chemical synthesis (A.4, D.1, D.2), machine learning (E.2, E.4), skills such as acquiring sources of information (A.1, A.4, B.1, B.3, B.5, D.1, D.2, E.1, E.2, E.3, E.4), and abilities such as business model innovation.

The improved speed it took to innovate business models shows one human capital outcome. It took time (and persistence) to accumulate the human capital necessary to develop

and innovate business models. Alternatively, the less one knows about a market, the longer it will take them to come to a profitable business model. The size of the learning curve can determine how long it may take. While the total time it took to assess the different business models decreased over time, the design of each model benefited from the lessons learned from the previous model. This is an example of an improved ability to create a new hypothesis, acquire and process relevant information to test the hypothesis, and put the findings through an operational lens. The human capital accumulated during the process was converted into new employment opportunities that did not exist before. This supports previous findings on the role of human capital outcomes in entrepreneurship (Davidsson and Honig, 2003; Unger et al., 2011) and the importance of leadership/management cognitive abilities in business model innovation (Foss and Saebi, 2017).

Chapter 6: Conclusion

While it is well known that start-ups change their business models, there has been little empirical research on why and how those changes are made. This thesis sought to answer the research question: why and how do start-ups change their business model? Understanding human capital is part of the answer.

This thesis has shown that business models are changed because founders *believe* that the business model is not, or cannot be, profitable OR that there is a more profitable and scalable option within reach. What is believed is highly subjective. Therefore, the perceived potential of an opportunity depends on the background of the individual and the nature of the opportunity (Shane, 2003). Not every opportunity is for everyone. However, this thesis has also provided evidence that the accumulation of human capital outcomes can change (improve or worsen)

one's perception of an opportunity and the nature of the opportunity itself. As a result, business models are changed by discovering new markets or customer use cases and arranging the resources, capabilities, network allies, and operations necessary to achieve the desired impact. Discovering new markets or customer use cases is a human capital-intensive undertaking since key pieces of information can go unnoticed or misinterpreted.

Overall, we can conclude from the data and analysis that start-up business models improve over time with investment into various types of human capital. The accounts with the most impact on the business model came from new informants, so the access to, and value of, social networks may also be a contributing factor. Similarly, the less human capital one has about a particular matter, the more time and effort will be needed to design a potentially valuable business model. That is not to dissuade entrepreneurs from undertaking projects in which they are not experts, but rather a warning that you will miss a lot of vital information early on, and it will require more time and patience than you anticipate. A strong and ever-evolving group of advisors can help.

A major limitation of this thesis is that the business models were short-lived and not fully explored. While the findings support the importance of profitability, it is uncertain whether the models were indeed profitable or not because they were changed based on feedback rather than performance. Nonetheless, it contributes to the literature by providing empirical evidence of why and how start-ups change their business models by providing analysis of six versions of the business model canvas. This will hopefully serve as a guide for how different versions of business models can be assessed in the future. Further research is also needed on the impact and role of other components of the business model canvas in BMI, and to what extent research on established firms can apply to start-ups, or vice versa.

References

Aldrich, H. E., & Yang, T. (2012). What did Stinchcombe really mean? Designing research to test the liability of newness among new ventures. Entrepreneurship Research Journal, 2(3).

Barney, J. (1991). Firm resources and sustained competitive advantage. Journal of management, 17(1), 99-120.

Ball, P. (2016). Computer gleans chemical insight from lab notebook failures. Nature News.

Baškarada, S. (2014). Qualitative case study guidelines. Baškarada, S.(2014). Qualitative case studies guidelines. The Qualitative Report, 19(40), 1-25.

Becker, G. S. (1975). Investment in human capital: effects on earnings. In Human Capital: A Theoretical and Empirical Analysis, with Special Reference to Education, Second Edition (pp. 13-44). NBER.

Blank, S. (2013). Why the lean start-up changes everything. Harvard Business Review, 91(5).

Blank, S. (2020). The four steps to the epiphany: successful strategies for products that win. John Wiley & Sons.

Burnell, D., Stevenson, R., & Fisher, G. (2023). Early-stage business model experimentation and pivoting. Journal of Business Venturing, 38(4), 106314.

Briody, E. K., & Stewart, A. (2019). Entrepreneurship: A challenging, fruitful domain for ethnography. Journal of Business Anthropology, 8(2), 141-166.

Chesbrough, H. W. (2007). Why companies should have open business models. MIT Sloan management review.

Chesbrough, H. W., & Appleyard, M. M. (2007). Open innovation and strategy. California management review, 50(1), 57-76.

Chesbrough, H. (2010). Business model innovation: opportunities and barriers. Long range planning, 43(2-3), 354-363.

Cohen, S. L., Bingham, C. B., & Hallen, B. L. (2019). The role of accelerator designs in mitigating bounded rationality in new ventures. Administrative Science Quarterly, 64(4), 810-854.

Coley, C. W., Green, W. H., & Jensen, K. F. (2018). Machine learning in computer-aided synthesis planning. Accounts of chemical research, 51(5), 1281-1289.

Corey, E. J., Long, A. K., & Rubenstein, S. D. (1985). Computer-assisted analysis in organic synthesis. Science, 228(4698), 408-418.

Davidsson, P., & Honig, B. (2003). The role of social and human capital among nascent entrepreneurs. Journal of business venturing, 18(3), 301-331.

Denshire, S., & Lee, A. (2013). Conceptualizing autoethnography as assemblage: Accounts of occupational therapy practice. International Journal of Qualitative Methods, 12(1), 221-236.

Díaz-Díaz, R., Muñoz, L., & Pérez-González, D. (2017). The business model evaluation tool for smart cities: Application to SmartSantander use cases. Energies, 10(3), 262.

Dimov, D. (2010). Nascent entrepreneurs and venture emergence: Opportunity confidence, human capital, and early planning. Journal of management studies, 47(6), 1123-1153.

Flyvbjerg, B. (2006). Five misunderstandings about case-study research. Qualitative inquiry, 12(2), 219-245.

Foss, N. J., & Saebi, T. (2017). Fifteen years of research on business model innovation: How far have we come, and where should we go?. Journal of management, 43(1), 200-227.

Gartner, W. B. (1988). "Who is an entrepreneur?" is the wrong question. American journal of small business, 12(4), 11-32.

Geissdoerfer, M., Vladimirova, D., & Evans, S. (2018). Sustainable business model innovation: A review. Journal of cleaner production, 198, 401-416.

George, G., & Bock, A. J. (2011). The business model in practice and its implications for entrepreneurship research. Entrepreneurship theory and practice, 35(1), 83-111.

Gerring, J. (2004). What is a case study and what is it good for?. American political science review, 98(2), 341-354.

Glaser, B., & Strauss, A. (1967) The discovery of grounded theory: Strategies for qualitative research. Chicago: Aldine.

Hannan, M. T., & Freeman, J. (1984). Structural inertia and organizational change. American sociological review, 149-164.

Hsieh, D. S., Lindrud, M., Lu, X., Zordan, C., Tang, L., & Davies, M. (2017). A process for active pharmaceutical ingredient recovery from tablets using green engineering technology. Organic Process Research & Development, 21(9), 1272-1285.

Karthikeyan, A., & Priyakumar, U. D. (2022). Artificial intelligence: machine learning for chemical sciences. Journal of Chemical Sciences, 134, 1-20.

Massa, L., Tucci, C. L., & Afuah, A. (2017). A critical assessment of business model research. Academy of Management annals, 11(1), 73-104.

Marvel, M. R., Davis, J. L., & Sproul, C. R. (2016). Human capital and entrepreneurship research: A critical review and future directions. Entrepreneurship Theory and Practice, 40(3), 599-626.

Morris, M., Schindehutte, M., & Allen, J. (2005). The entrepreneur's business model: toward a unified perspective. Journal of business research, 58(6), 726-735.

Osterwalder, A., & Pigneur, Y. (2010). Business model generation: a handbook for visionaries, game changers, and challengers (Vol. 1). John Wiley & Sons.

Pratama, D. E., Hsieh, W. C., Elmaamoun, A., Lee, H. L., & Lee, T. (2020). Recovery of active pharmaceutical ingredients from unused solid dosage-form drugs. ACS omega, 5(45), 29147-29157.

Poláková, J., Koláčková, G., & Tichá, I. (2015). Performance implications of business model change: a case study. Acta Universitatis Agriculturae et Silviculturae Mendelianae Brunensis, 63(6), 2101-2107.

Pollak, P. (2011). Fine chemicals: the industry and the business. John Wiley & Sons.

Quinn, M. (2015, March 29). *20,000 unused, old medications collected at St. John's pill drop.* CBC. https://www.cbc.ca/news/canada/newfoundland-labrador/20-000-unused-old-medications-collected-at-st-john-s-pill-drop-1.3014072

Unger, J. M., Rauch, A., Frese, M., & Rosenbusch, N. (2011). Human capital and entrepreneurial success: A meta-analytical review. Journal of business venturing, 26(3), 341-358.

Raccuglia, P., Elbert, K. C., Adler, P. D., Falk, C., Wenny, M. B., Mollo, A., ... & Norquist, A. J. (2016). Machine-learning-assisted materials discovery using failed experiments. Nature, 533(7601), 73-76.

Reis, E. (2011). The lean startup. New York: Crown Business, 27, 2016-2020

Rodriguez, N. M., & Ryave, A. (2002). Systematic self-observation: A method for researching the hidden and elusive features of everyday social life (Vol. 49). Sage.

Schneider, S., & Spieth, P. (2013). Business model innovation: Towards an integrated future research agenda. International Journal of Innovation Management, 17(01), 1340001.

Schultz, T. W. (1961). Investment in human capital. The American economic review, 51(1), 1-17.

Shane, S. A. (2003). A general theory of entrepreneurship: The individual-opportunity nexus. Edward Elgar Publishing.

Shane, S., & Venkataraman, S. (2000). The promise of entrepreneurship as a field of research. Academy of management review, 25(1), 217-226.

Sharma, M., Kumar, A., & Chaudhary, A. (2019). Reuse API (active pharmaceutical ingredients) from expired dosage form. Int J Eng Res Technol, 8(6), 276-298.

Shepherd, D. A., & Gruber, M. (2021). The lean startup framework: Closing the academic–practitioner divide. Entrepreneurship Theory and Practice, 45(5), 967-998.

Stockwell, B. R. (2011). The quest for the cure: the science and stories behind the next generation of medicines. Columbia University Press.

Teece, D. J. (2010). Business models, business strategy and innovation. Long range planning, 43(2-3), 172-194.

Tsang, E. W. (2014). Generalizing from research findings: The merits of case studies. International Journal of Management Reviews, 16(4), 369-383.

Venkataraman, S. (2019). The distinctive domain of entrepreneurship research. In Seminal ideas for the next twenty-five years of advances (pp. 5-20). Emerald Publishing Limited.

Vittori, D., Natalicchio, A., Panniello, U., Petruzzelli, A. M., & Cupertino, F. (2022). Business Model Innovation between the embryonic and growth stages of the industry lifecycle. Technovation, 117, 102592.

Wasserman, N. (2013). The founder's dilemmas: Anticipating and avoiding the pitfalls that can sink a startup. Princeton University Press.

Wess, G., Urmann, M., & Sickenberger, B. (2001). Medicinal chemistry: challenges and opportunities. Angewandte Chemie International Edition, 40(18), 3341-3350.

World Health Organisation. (2011). “Guidelines for Medication Donations”.

Zilker, M., Sörgel, F., & Holzgrabe, U. (2019). A systematic review of the stability of finished pharmaceutical products and drug substances beyond their labeled expiry dates. Journal of pharmaceutical and biomedical analysis, 166, 222-235.

Zott, C., & Amit, R. (2007). Business model design and the performance of entrepreneurial firms. Organization science, 18(2), 181-199.

Zott, C., Amit, R., & Massa, L. (2011). The business model: recent developments and future research. Journal of management, 37(4), 1019-1042.