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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number 001-37718

F-STAR THERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**52-2386345**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
B920 Babraham Research Campus Cambridge, United Kingdom CB22 3AT	**N/A**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: +44-1223-497400

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value	**FSTX**	**The Nasdaq Stock Market (Nasdaq Capital Market)**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Stock Market on June 30, 2020, was $23.4 million.

The number of shares of Registrant's Common Stock outstanding as of March 24, 2021 was 9,100,320.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A relating to the 2021 Annual Meeting of Stockholders within 120 days of the end of the registrant's fiscal year ended December 31, 2020. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein.

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PRESENTATION OF FINANCIAL INFORMATION

On November 20, 2020, Spring Bank Pharmaceuticals, Inc. acquired all of the outstanding capital stock of F-star Therapeutics Limited. While Spring Bank Pharmaceuticals, Inc. was the legal acquirer of F-star Therapeutics Limited in the transaction, F-star Therapeutics Limited was deemed to be the acquiring company for accounting purposes. As such, the transaction was accounted for as a reverse recapitalization in accordance with accounting principles generally accepted in the United States of America, and Spring Bank Pharmaceuticals, Inc.'s historical financial statements have been replaced with F-star Therapeutics Limited's historical financial statements. The historical financial statements of Spring Bank Pharmaceuticals, Inc. are not included in this Annual Report. All common share, additional paid-in capital and per share amounts in the consolidated financial statements and related notes have been retrospectively adjusted to reflect the Exchange Ratio (as defined herein).

PART I

Item 1. Business.

Overview

We are a clinical-stage biopharmaceutical company dedicated to developing next generation immunotherapies to transform the lives of patients with cancer. Our goal is to offer patients better and more durable benefits than currently available immuno-oncology treatments by developing medicines that seek to block tumor immune evasion. Through our proprietary tetravalent, bispecific natural antibody (mAb²™) format, our mission is to generate highly differentiated medicines with monoclonal antibody-like manufacturability, good safety and tolerability. With four distinct binding sites in a natural human antibody format, we believe our proprietary technology will overcome many of the challenges facing current immuno-oncology therapies, due to the strong pharmacology enabled by tetravalent bispecific binding.

Our most advanced product candidate, FS118, is currently being evaluated in a proof-of-concept Phase 2 trial in PD-1/PD-L1 acquired resistance head and neck cancer (''H&N'') patients. FS118 is a tetravalent mAb² bispecific antibody targeting two receptors, PD-L1 and LAG-3, both of which are established pivotal targets in immuno-oncology. Phase 1 data from 43 heavily pre-treated patients with advanced cancer, who have failed PD-1/PD-L1 therapy, showed that administration of FS118 was well-tolerated with no dose limiting toxicities up to 20 mg/kg. In addition, a disease control rate (''DCR''), defined as either a complete response, partial response or stable disease, of 49% was observed in 39 evaluable patients receiving dose levels of FS118 of 1mg/kg or greater. In acquired resistance patients, DCR was 59% (16 out of 27 patients) and long-term (greater than six months) disease control was observed in six of these patients. We expect to provide an update from the proof-of-concept Phase 2 trial in PD-1/PD-L1 acquired resistance head and neck cancer patients in H1 2022.

In our second program, FS120, we initiated a Phase 1 clinical trial in patients with advanced cancers in late 2020. FS120 is a first-in-class dual agonist bispecific antibody, an antibody that stimulates two immune activating pathways, which we believe has the potential to overcome cancer resistance by stimulating CD137 (4-1BB) and OX40, two receptors present on the surface of tumor-infiltrating lymphocytes. Unlike checkpoint inhibitors (''CPI''), the mechanism of action of FS120 is designed to trigger a positive signal that enhances multiple mechanisms essential for killing tumor cells. FS120 may provide increased specificity and, we believe, superior performance while reducing toxicity through engineered conditional, crosslink-dependent activation upon binding to both CD137 and OX40. We expect to enroll up to 70 patients in the Phase 1 dose escalation clinical trial to assess the safety, tolerability and efficacy of FS120 in patients with advanced malignancies and include those patients who have high co-expression of CD137 and OX40. We expect to provide an update on study progress in mid-2021.

Our third bispecific program from our proprietary platform, FS222, began a Phase 1 clinical trial for FS222 in patients with advanced cancers in late 2020. FS222 has the potential to provide clinical benefit through multiple mechanisms based on its tetravalency, including (1) blocking the PD-1/PD-L1 immunosuppressive pathway and (2) conditionally clustering and crosslinking CD137 receptors, resulting in activation of CD137 in a PD-L1-dependent manner. We believe this dual mechanism of action could lead to strong anti-tumor activity including benefits in cancers with low PD-L1 expression. Our preclinical data shows that FS222 has the potential to be more effective than a combination of traditional PD-L1 and CD137 antibodies. PD-L1 is frequently highly expressed on cells within cancer tissue compared to non-cancer tissue. Therefore, we believe this will make FS222's immune activation conditional within cancer tissue, limit potential systemic toxicities and lead to safety benefits. We expect to initiate a Phase 1 expansion cohort to measure pharmacokinetic (PK)/ pharmacodynamic (PD) profiles for FS222 in Q4 2021

In addition to the mAb² product candidates, we are evaluating SB 11285 in a Phase 1 clinical trial as an intravenously (''IV'') administered monotherapy, and in combination with a commercially approved anti-PD-L1 antibody, in patients with advanced cancers. SB 11285 is a next generation cyclic dinucleotide-based stimulator

of interferon genes (''STING'') agonist with efficient cellular uptake. We believe that SB 11285 has the potential to produce anti-tumor activity by inducing interferon pathways and activating the innate and, indirectly, the adaptive immune system. We believe combining SB 11285 with PD-L1 therapy will further enhance anti-tumor activity. SB 11285 has been designed to allow IV administration which we believe will increase its applicability to treat a wide variety of advanced cancers. We expect to report an update on the trial in mid-2021.

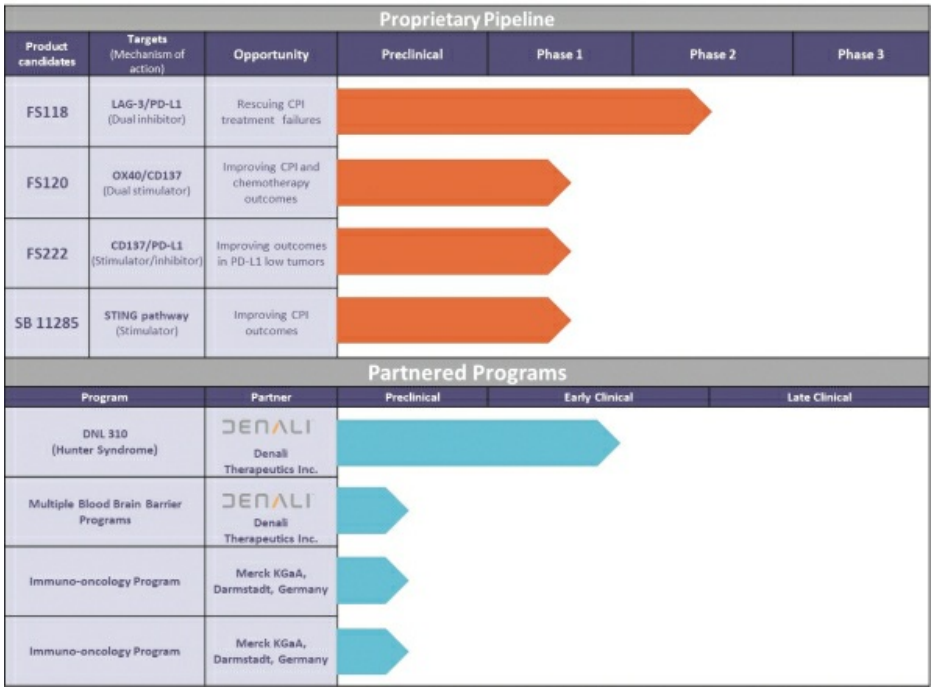
In 2020, combined sales of current immuno-oncology therapies were estimated to be approximately $28.7 billion. Despite the commercial success of currently approved immuno-oncology products, only approximately 20% of patients realize a long-lasting benefit from these treatments, leaving a large, unserved patient population without effective treatment options.

We believe our mAb^2 bispecific antibodies may address the limitations of current immuno-oncology therapies through the following advantageous characteristics that differentiate our mAb^2 product candidates:

- *Novel Tetravalent Format*. We engineer our mAb^2 bispecific antibodies to simultaneously bind two different targets, with two binding sites for each target. The ability to bind in this way is known as tetravalency. This unique tetravalent format is designed to enable our mAb^2 bispecific antibodies to achieve more efficient crosslinking, clustering or conditionality than other bispecific antibodies, and therefore have the potential to elicit improved biological responses and enable our mAb^2 bispecific antibodies to overcome tumor evasion pathways. These three key characteristics are described further below:
  - *Crosslinking*. Crosslinking is the act of bringing either two target-bearing cells, or two targets on the same cell, into close proximity. The dual binding sites for each target, within our bispecific antibodies, enables durable and strong target crosslinking through the ability to engage with target-bearing cells simultaneously, for example, engaging both tumor cells and immune cells.
  - *Clustering.* Many cellular receptors can only be optimally activated when many of those receptors are brought into close physical proximity on the cell surface, referred to as “clustering”. Since our mAb^2 bispecific antibodies have F-star’s distinct binding sites, they can potentially induce more potent clustering than non-tetravalent bispecific antibody formats.
  - *Conditionality.* Conditionality occurs when immune activation is dependent on the bispecific antibody binding both targets simultaneously, often in the tumor microenvironment. We are able to leverage the prospectively engineered tetravalent format of our mAb^2 bispecific antibodies so that targets are only activated when they are simultaneously bound.
- *Natural Human Antibody Format.* Our mAb^2 bispecific antibodies are designed to conserve the natural human antibody format, with greater than 95% identity, allowing us to leverage the following advantages:
  - *Minimal systemic toxicity.* Since our mAb^2 bispecific antibodies use a natural human antibody format, without synthetic linkers and domains, there is lower potential for systemic toxicity than traditional and bispecific antibodies.
  - *Low immunogenicity risk.* The natural human antibody format of our mAb^2 bispecific antibodies and the low number of modifications we engineer into our mAb^2 bispecific antibodies is designed to help mitigate immunogenicity risk, or the risk that the immune system recognizes the mAb^2 bispecific antibody as foreign, potentially resulting in lower exposure and toxicity.
  - *Ease of manufacturability.* We are able to produce our mAb^2 bispecific antibodies through established manufacturing processes readily and at large scale with typical industry time and cost standards and without potentially complicating additions, such as domain assembly or other modifications.

We believe the novel tetravalent and natural human antibody formats of our mAb 2 bispecific antibodies have the potential to focus immune activation to enhance efficacy and reduce systemic toxicities.

The following table sets forth our product candidates and their current development stages.



Abbreviations: LAG-3, lymphocyte activation gene 3; PD-L1, programmed death-ligand 1; CD137, cluster of differentiation 137; OX40, also known as cluster of differentiation 134; STING, stimulator of interferon genes; CPI: checkpoint inhibitors

The tetravalent format of FS118 simultaneously targets two immune checkpoint receptors, LAG-3 and PD-L1, to directly address known tumor evasion pathways. FS118 is currently being evaluated in a proof-of-concept Phase 2 trial in PD-1/PD-L1 acquired resistance head and neck cancer patients. In the Phase 1 clinical trial in heavily pretreated patients with advanced cancer who have failed PD-1/PD-L1 therapy it was demonstrated that administration of FS118 was well-tolerated and has provided long-term disease control. FS120 and FS222 are currently being evaluated for safety, tolerability and efficacy in Phase 1 clinical trials in patients with advanced cancers. SB 11285 is a next generation cyclic dinucleotide-based STING agonist that is being evaluated for safety, tolerability and efficacy as a monotherapy and in combination with an anti-PD-L1 antibody in a Phase 1 clinical trial with advanced cancers. Our portfolio includes further preclinical and clinical programs that are being developed by our partners as described below under " Collaborations and License Agreements".

We leverage our proprietary mAb 2 technology to build our portfolio of wholly owned immuno-oncology mAb 2 product candidates and have generated a panel of early stage Fcab, Fc with antigen binding, building

blocks against a range of targets with the potential to go beyond immuno-oncology. These Fcab building blocks have been used to generate not only bispecific antibodies but also trispecific antibodies and fusion proteins. We have over 230 granted patents and over 150 pending applications relating to our mAb^2 technology and our product pipeline. We believe we have a leading position in mAb ^{2} bispecific antibody development, and third parties are prohibited from utilizing our mAb^2 technology without obtaining a license from us.

We have collaborative partnerships with Ares Trading S.A., an affiliate of Merck KGaA, Darmstadt, Germany, and Denali Therapeutics Inc., which enable us to further validate our technological approach. Since inception, the F-star entities which have entered into collaborations, which are F-star Alpha Limited, F-star Beta Limited, F-star Biotechnology Limited and F-star Delta Limited, have collectively generated over $167 million in revenue to date, $90 million of which has been included in the cumulative equity of the Company. We believe that these partnerships will provide both continued validation and ongoing revenue as we continue to advance our proprietary pipeline.

We are led by a team of highly experienced executives, clinicians, scientists and advisors with notable expertise in antibody research, immuno-oncology, antibody manufacturing and clinical development. Our team has spent over a decade developing our proprietary mAb^2 technology into a robust drug discovery platform. Our team has collectively worked on the development of 20 marketed products and has worked at companies including AstraZeneca, BMS, Celgene Corporation, Domantis, Eli Lilly, GSK, Immunocore and Pfizer (“Pfizer”).

Strategy

We are dedicated to developing next generation immunotherapies to transform the lives of patients with cancer by generating highly differentiated, first and/or best-in-class product candidates. The key elements of our strategy include:

- ***Rapidly accelerating the clinical development of our three novel mAb ^{2} product candidates and novel cyclic dinucleotide, SB 11285, to treat a range of advanced cancers.*** We believe our mAb^2 product candidates represent potentially best-in-class immuno-oncology therapies that address a variety of patients with cancer inadequately treated with existing therapies. We believe FS118, which is being evaluated in a proof-of-concept Phase 2 trial in PD-1/PD-L1 acquired resistance head and neck cancer patients, has the potential to provide significant clinical benefit through its dual-checkpoint inhibitor targets (LAG-3 and PD-L1). In addition to FS118, we are currently evaluating FS120, FS222 and SB 11285 for safety, tolerability and efficacy in Phase 1 clinical trials in patients with advanced cancers. All of our product candidates have the potential to address multiple immune evasion pathways that limit the effect of current immuno-oncology therapies.
- ***Initially focusing our development strategy on tumors where checkpoint inhibitors are currently utilized but are poor long-term treatment options, and then subsequently broadening to other tumor types.*** Our early-stage clinical trials include or will include a broad range of tumor types to evaluate safety, tolerability and dosing, as well as early signals of efficacy. Following these early-stage clinical trials, we intend to employ a patient selection strategy, using biomarkers to focus further development on targeted patient subsets. These subsets are expected to include patients with high cancer target co-expression and/or resistance to current checkpoint therapies. We believe our mAb^2 bispecific antibodies and SB 11285 may also ultimately deliver therapeutic benefit in a broader range of tumors, expanding beyond the initial indications we may pursue. We believe our development strategy best serves the patient, can be efficiently pursued by our organization, and has the potential to lead to a rapid development strategy and regulatory pathway to market. For example, we have identified several tumor types which have a strong fit with the potential FS118 mechanism of action, including appropriate target expression that would be candidates for accelerated approval pathways.
- ***Leveraging the transformational potential of our modular antibody technology platform to create a leading immuno-oncology pipeline of differentiated clinical assets capable of improving patient outcomes.*** We believe our proprietary mAb^2 bispecific antibodies have a number of potential advantages, compared to other modalities, resulting from their novel tetravalent and natural human

antibody formats, which may result in improved efficacy, minimized toxicity and simplified manufacturability. We believe our technology has the potential to be matched with any disease target in a modular "plug-and-play" approach to further expand our innovative pipeline of mAb^2 product candidates. We also believe these benefits may provide multiple opportunities to consistently generate clinical candidates that could potentially address the needs of patients who are without adequate therapeutic options.

- ***Leveraging and continuing to build our extensive intellectual property portfolio in order to protect our dominant position in mAb^2 bispecific antibodies and our STING agonist program.*** We have built an extensive patent portfolio around our mAb^2 technology and associated mAb^2 product pipeline. In addition, we have STING pathway-related filings, including those of a patent family relating to the composition of matter of the STING agonist SB 11285. This patent estate relates to our mAb^2 bispecific format and STING agonist program and aims to provide us with robust intellectual property exclusivity and prohibit use of our technology by third parties. We intend to continue to seek additional patent protection as we develop additional novel mAb^2 product candidates.

The Immuno-oncology Challenge and our mAb^2 Technology

Cancer Treatment Overview

The incidence of cancer is increasing due to the aging of the world population, as well as an increasing prevalence in individuals with known risk factors. Based on GLOBOCAN 2020 estimates, approximately 19.2 million new cancer cases were diagnosed, and 9.9 million cancer deaths occurred in 2020 worldwide. Cancer treatment has traditionally included chemotherapy, radiation, hormone therapy, surgery or a combination of these approaches. While these approaches can be effective in treating certain types of cancers, many can also cause toxicities that may have life-threatening consequences, lower quality of life or untimely termination of treatment. Furthermore, we believe the traditional therapeutic approaches have reached their efficacy plateau with limited room to prolong the patient's life expectancy. More recently, cancer research has leveraged antibody approaches to target the emerging field of immuno-oncology, which aims to enhance natural anti-tumor immune responses by, for example, overcoming mechanisms that cancer cells have developed to evade the immune system. Initially, antibody approaches were developed for treatment in second- or third-line settings but, recently, have become more common as the standard of care, first-line treatment for a variety of tumor types, including non-small cell lung cancer, melanoma, renal cell carcinoma, liver cancers, gastric cancers and head and neck cancers, amongst others. We believe this has created a significant treatment gap and new unmet need for the majority of patients whose disease becomes resistant to those antibodies.

Successes and Limitations of Immuno-oncology

Under normal conditions, cell surface proteins known as immune checkpoints help to control T cell attacks on healthy cells in the body. The activity of stimulatory checkpoints that activate or "hit the gas" on immune response is balanced by inhibitory checkpoints that inactivate or "apply the brake" on the immune response. The immune system recognizes cancers and mobilizes special immune cells known as lymphocytes, which are primarily T cells and B cells, to attack the tumor. A specific type of lymphocyte with the capacity to recognize and attack the tumor, known as tumor infiltrating lymphocytes ("TILs"), travel to and infiltrate into the tumor. However, the anti-tumor effect of the TIL is usually short-lived, as some cancer cells overexpress inhibitory immune checkpoints, which suppress the immune system and enable the tumor cells to evade elimination. Popular immuno-oncology approaches to enhance anti-tumor immune responses include the use of traditional monoclonal antibodies, which we refer to as traditional antibodies, antibody combinations and bispecific antibodies to overcome these immune checkpoint blockades and engage the immune system to fight the cancer. One of the few approved approaches involves the use of traditional antibodies that turn off certain inhibitory checkpoints. The use of traditional antibodies to activate stimulatory checkpoints within the immune system is also being explored extensively, but with less notable clinical success to date.

One of these inhibitory checkpoints, programmed cell death protein 1 ("PD-1"), is expressed on T cells and can be controlled by programmed cell death ligand 1 ("PD-L1"), which is a protein that is overexpressed by some tumors in an attempt by the tumor to inhibit natural immune response. Traditional antibody therapeutics against PD-1 or PD-L1 have been transformational for some patients with long-lasting tumor control. However, large patient populations are resistant. Resistance to PD-1/PD-L1 regimens can come in two main forms. "Primary Resistance" is where the cancer shows no sensitivity to treatment and continues to grow. "Acquired Resistance" to PD-1/PD-L1 regimens, sometimes referred to as secondary resistance, is where there is initial sustained (greater than or equal to three months) clinical benefit (defined as a complete response, partial response, or stable disease) from therapy but the cancer then starts to grow again while the patient is still being treated. A meta-analysis of data from several well-controlled clinical trials with PD-1 or PD-L1 therapeutic antibodies indicated that responses were seen in only approximately 20% of treated patients, compared to approximately 9% of control patients, using RECIST (response evaluation criteria in solid tumors) criteria. Besides PD-1/PD-L1, it is generally believed that there are multiple other immuno-oncology checkpoint targets with the potential to improve patient response rates alone or when used in combination.

Other Antibody Approaches in Immuno-oncology

One approach to address patient populations with Primary or Acquired Resistance on monotherapy is the use of a combination of two traditional antibodies to inhibit and/or activate two checkpoint pathways at the same time. Such traditional antibody combination treatment has been shown to have some success in limited settings, leading to an additive clinical benefit. The combination of PD-1 and cytotoxic T-lymphocyte-associated protein 4 ("CTLA-4"), antibodies, for example, increases overall survival of melanoma patients when compared to CTLA-4 monotherapy (37.6 months versus 19.9 months, respectively). However, the toxicity observed when PD-1 and CTLA-4 antibodies are used individually (21% and 28%, respectively, grade 3 or 4 adverse events) is increased when they are used in combination (59% grade 3 or 4 adverse events). This increased toxicity has limited the clinical application of this combination approach. Additionally, using two traditional antibodies can increase costs and administrative burden to patients, physicians and the broader healthcare system.

The goal of targeting two cancer pathways at the same time can also be achieved by bispecific antibodies, which have several benefits over existing mono- or combination therapies. This approach builds on the strengths of using a combination of two traditional antibodies and potentially addresses some of their limitations. Generally, bispecific antibodies have the potential to elicit improved biological responses relative to traditional antibodies or combinations thereof. Some bispecific antibodies are able to achieve improved responses through the deployment of one or more of crosslinking, clustering and conditionality, which we refer to collectively as the "3Cs":

- *Crosslinking.* Crosslinking is the act of bringing either two target-bearing cells, or two targets on the same cell, into close proximity for optimal biological effect. As a result of this crosslinking, bispecific antibodies have the potential to induce novel desirable biological responses. Binding to two different cells, for example a tumor cell and a T cell, can result in the recruitment of T cells to the tumor site, thereby increasing the anti-tumor activity, as well as reducing toxicity. We believe that optimal crosslinking is dependent on the relative affinities for both cellular targets and the geometry of the bispecific antibody.
- *Clustering.* Much of the regulation of the immune system occurs through cell-surface proteins known as receptors. Many cellular receptors can only be optimally activated when many of those receptors are brought into close physical proximity on the cell surface, referred to as "clustering." By binding two target receptors, bispecific antibodies can group together the receptors on the cell, leading to activation of certain receptors. In the context of modulating the immune response, receptor clustering and activation can increase the likelihood of anti-tumor activity.
- *Conditionality.* The binding of a bispecific antibody to both antigens can induce immune activation. Conditionality occurs when immune activation is dependent on the bispecific antibody binding both

targets simultaneously, usually in the tumor microenvironment. Conversely, where one antigen is bound by the bispecific antibody resulting in immune activation without the need for simultaneous binding to the other target, conditionality does not exist. When there is conditional activity, increased localized anti-tumor activity can be elicited, while, in the absence of conditional activity, there is greater risk for systemic toxicity.

When bispecific antibodies can achieve the 3Cs, they may be able to concentrate their activity at the tumor site, potentially increasing efficacy with an improved safety profile. Moreover, since bispecific antibodies are a single-infused product, they offer administrative benefits for patients and healthcare professionals as compared to a combination of traditional antibodies that are individually infused.

Many different molecular design approaches have been taken to create bispecific antibodies against a range of target pairings. These include heterodimeric bispecific IgG antibodies and alternative scaffold bispecific antibodies. These all aim to achieve the aforementioned characteristics of the 3Cs but can be limited by relative affinities, valency and molecular geometry and in addition are often harder to manufacture.

Heterodimeric Bispecific IgG Antibodies

Heterodimeric bispecific antibodies seek to conserve the native architecture of the IgG molecule by incorporating asymmetric chain pairings into the same molecule such that each of the two binding sites in the Fragment variable (“Fv”), region of the antibody structure is able to bind different targets. This structure supports bispecific crosslinking of targets but is limited to monovalent binding at each of these sites, meaning they cannot achieve tetravalent clustering. The strong conservation of the native IgG architecture supports IgG-like manufacturing.

Alternative Scaffold Bispecific Antibodies

Another approach to achieving bispecificity is to engineer modular antibody target binding domains, or “fragments,” into so-called “alternative scaffolds.” Alternative scaffolds take many forms, some of which can achieve tetravalent bispecificity and support target crosslinking. However, such approaches result in a significant departure from the natural IgG architecture which can result in a variety of problems. One such approach could involve combining two different antibody fragments to bind to two targets. However, such architecture lacks important regions that protect the molecule from natural breakdown in circulation by the neonatal fragment crystallizable (“Fc”), receptor, resulting in a potentially short half-life or lessened persistence. Other approaches to alternative scaffolds involve “bolting on” such antibody fragments to natural IgG antibodies. In these cases, manufacturing of the molecules becomes a significant challenge. In addition, the departure from the natural antibody structure increases immunogenicity risk.

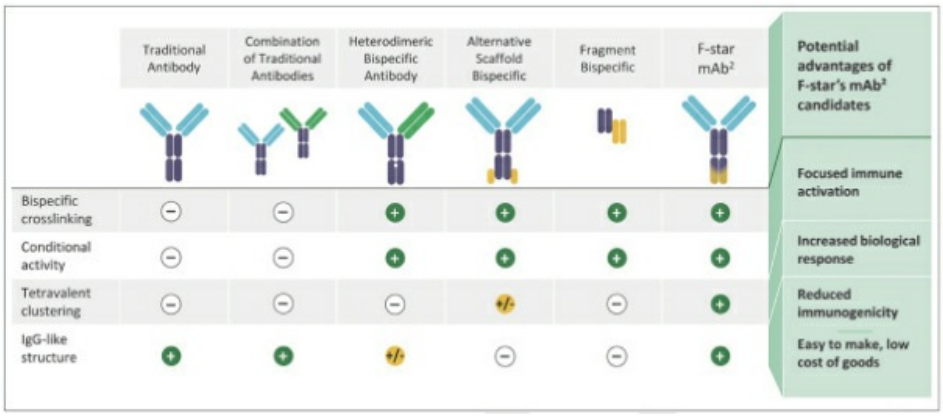
New Chemical Entity Approaches in Immuno-oncology

New chemical entity (“NCE”)-based immune therapies offer an additional approach to enhance the anti-tumor response. Among these are compounds that can target immune suppressive mechanisms or activate pathways in innate and/or adaptive immune cells that biologic therapies, such as antibodies, are not capable of accessing. Additional advantages of NCEs over biologics include oral bioavailability, greater tumor penetration, and the ability to cross cell membranes to access intracellular targets. The diverse types of immune cells, receptors, and molecular pathways implicated in responding to the tumor or in suppressing these responses offers a wide range of potential molecular targets. In general, these molecular targets correspond either to receptors such as Toll-like receptors or to enzymes involved in intracellular signal transduction. An example of an immunostimulatory NCE target is the stimulator of interferon genes (“STING”) which is a transmembrane protein localized to the endoplasmic reticulum. A conformational change of STING in response to direct binding of cyclic dinucleotides, results in a downstream signaling cascade, and production of Type-I interferons, including interferon-b, and other cytokines.

F-star mAb² Technology

Our platform is designed to effectively achieve the 3Cs whilst also conserving the natural human antibody format. We believe this natural human antibody format, with greater than 95% identity to the unmodified Fc region, is the ideal approach regarding safety and efficacy to target unmet medical needs in immuno-oncology.

Our mAb² Potential Advantages over Other Antibodies and Bispecific Antibodies



Novel Tetravalent Format

We believe our strong intellectual property position combined with over a decade of research and testing focused on the development of our proprietary technology put us in the unique position to produce mAb² bispecific antibodies through the introduction of an additional and proprietary second set of antigen binding sites into the Fc domain while also conserving the natural human antibody format. We believe we are differentiated in our approach in that we engineer mAb² bispecific antibodies to contain two independent antigen binding regions: (1) a dual binding site in the normal antibody antigen binding domains ("Fv portions"), of the antibody and (2) a second, proprietary, dual binding site introduced into the Fc portion of the antibody. We refer to this portion of a mAb² bispecific antibody as an Fcab (Fc with antigen binding). We engineer this unique tetravalent format to enable our mAb² bispecific antibodies to achieve more efficient crosslinking, clustering or conditionality than other bispecific antibodies. Our mAb² bispecific antibodies have the potential to elicit improved biological responses and overcome tumor evasion pathways, which we believe positions them as attractive candidates for clinical development.

- *Tetravalent crosslinking.* The tetravalent format of our mAb ² bispecific antibodies is designed to allow for more efficient target cell crosslinking than certain bispecific antibodies because there is an additional, second set of dual binding sites in the Fc region, and both sets can be engineered to engage with antigens that are found on both tumor cells and immune cells. For our mAb² product candidates that target tumor-associated antigens, such as PD-L1 (FS118 and FS222), crosslinking also supports safety by targeting the mAb² product candidates to the tumor, localizing the immune activation and thereby minimizing systemic toxicities.
- *Optimal clustering.* Antibodies with more than one binding site for a single receptor promote clustering of cellular receptors on the cell surface, resulting in robust activation of targets. Because each of our mAb² bispecific antibodies has our distinct binding sites, two for each antigen, they are designed to potentially induce more potent activation of multiple cellular receptors, including those on single cells,

than other bispecific antibodies. This is particularly useful for our mAb ^{2} product candidates FS120 and FS222, which activate the costimulatory molecule CD137 which clustering for potent activation.

- *Conditionality.* We combine bivalency for two targets with careful selection of target antigens to achieve optimal activation of the immune system, but only when both target antigens are present. For example, while some of our mAb^2 bispecific antibodies may be able to activate the immune system through binding to only one antigen, the greatest effect is expected to be seen when both antigens are bound at the same time, as observed with FS118. Additionally, through selection of target antigens and precise engineering of the dual antigen binding sites, we aim to increase the activity of our immunostimulatory mAb^2 bispecific antibodies at the tumor site, as observed with FS222 preclinically. We believe that we can potentially increase the safety of our mAb^2 product candidates compared to other bispecific antibodies which bind to their targets only monovalently and cannot be engineered for such optimal antigen binding.

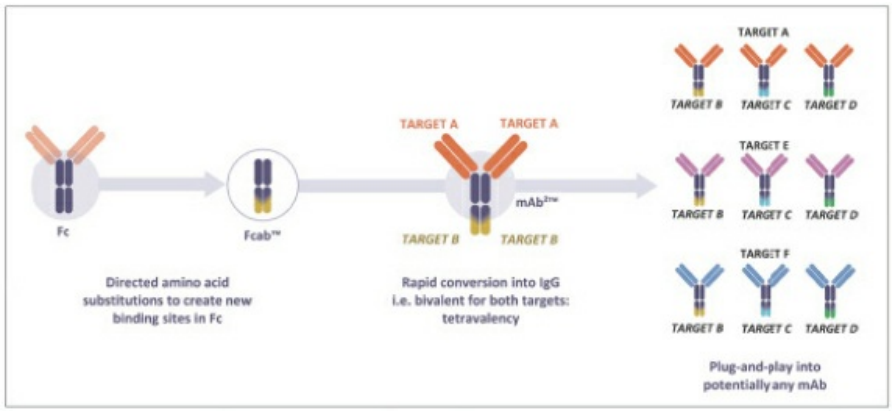
We believe, through our novel tetravalent format with bivalent binding to each target, that our mAb ^{2} bispecific antibodies have the potential to enhance efficacy and reduce potential for systemic toxicities.

Natural Human Antibody Format

Our mAb^2 bispecific antibodies are designed to conserve the natural human antibody format. With greater than 95% sequence identity to the equivalent traditional antibody, we are able to leverage the following advantages:

- *Plug-and-play*. We refer to our proprietary platform as modular antibody technology, because our library of Fcabs can be combined in a modular fashion with potentially any standard antibody antigen binding domains. This plug-and-play approach allows for rapid drug discovery to identify optimal target pairings, resulting in the creation of a broad portfolio of mAb^2 bispecific antibodies. Our Fcabs contain new target binding sites resulting from minimal modifications made in the Fc domain of the existing antibody structure. We routinely generate, in parallel, Fcabs that bind to human targets as well as those that bind to mouse targets. From these mouse Fcabs, we generate mouse mAb^2 bispecific antibody equivalents that can be used to test activity in animal models. The modular nature of the technology enables the rapid generation of novel mAb^2 product candidates.

F-star's Modular Antibody Technology



- *Minimized systemic toxicity.* Traditional antibodies targeting costimulatory molecules require engagement with Fc gamma receptors to induce target crosslinking, clustering and activation. However, binding to these receptors is often weak and the number of receptors is highly variable in tumor cells, which can lead to variable levels of immune cell activation. Additionally, engagement with Fc gamma receptors can result in binding to normal cellular receptors found in healthy cells, potentially resulting in systemic activation such as antibody-dependent cellular cytotoxicity ("ADCC"). Accordingly, we can engineer specific mutations in the Fc domain of our mAb^2 bispecific antibodies to prevent binding to Fc gamma receptors and eliminate Fc gamma receptor-mediated crosslinking. As a result, our mAb^2 bispecific antibodies can potentially improve immune activation while minimizing systemic toxicity.
- *Low immunogenicity risk.* The natural human antibody format of our mAb ^{2} bispecific antibodies and the low number of modifications we engineer into our mAb^2 bispecific antibodies is designed to help mitigate immunogenicity risk.
- *Ease of manufacturability.* We are able to produce our mAb ^{2} bispecific antibodies through established manufacturing processes readily and at large scale without potentially complicating additions, such as domain assembly or other modifications. Our mAb^2 bispecific antibodies also have pharmacologic properties consistent with other traditional antibody products, potentially allowing dosing to be adjusted based on patient response and off-the-shelf usage.

By leveraging these characteristics, which are demonstrated in the graphic below, we are developing a broad pipeline of mAb ^{2} product candidates.

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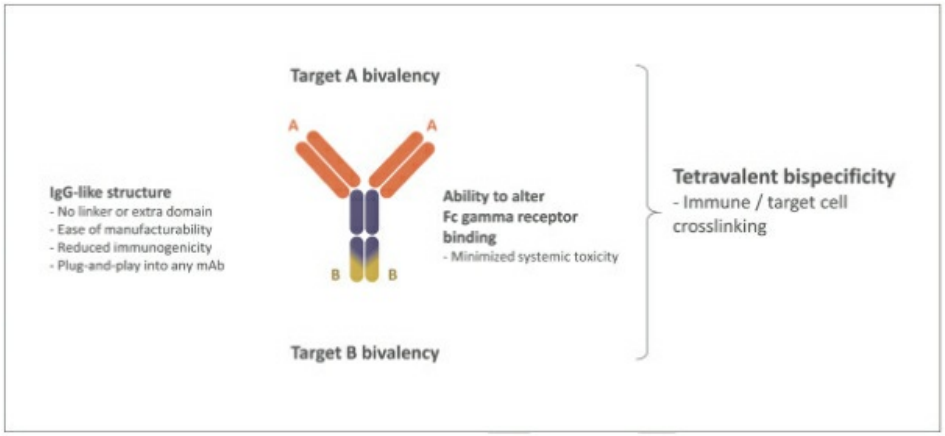


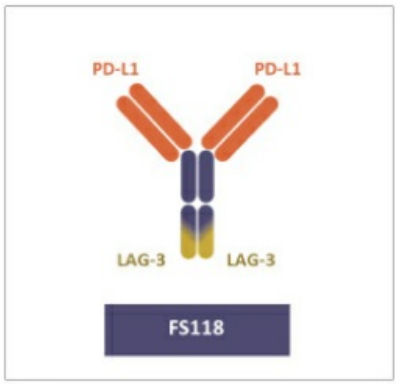
F-star Solution to the Unmet Medical Need in Immuno-oncology

In 2020, combined sales of current immuno-oncology therapies were approximately $28.7 billion worldwide. Despite the commercial success of these products, only approximately 20% of patients realize a long-lasting benefit from these treatments, leaving the majority, unserved patient population without effective treatment options. Our mAb^2 bispecific antibodies have the potential to overcome the limitations associated with current antibody therapies in immuno-oncology. They not only bind to two cancer targets at the same time, but the efficient receptor crosslinking and clustering of tumor and immune cells can also increase overall potency and biological response. Our current mAb^2 product candidates are directed against targets that have already demonstrated some level of activity in clinical trials using single traditional antibodies. The target pairings for our mAb^2 product candidates are selected on the basis of co-expression in tumors of defined patient populations with an unmet medical need, some of which have orphan status and would be candidates for accelerated approval. Our mAb^2 product candidates are progressed only if they demonstrated potential advantages in preclinical studies, such as safety and/or potency, beyond what would be achieved with the combination of two traditional antibodies and that are likely to differentiate from other bispecific antibody formats.

In addition to mAb^2 product candidates, we have a next generation NCE-based program to activate the immunostimulatory STING pathway. The synthetic cyclic dinucleotide-based STING agonist acts by activating the innate and, indirectly, the adaptive immune system, which in combination with PD-1/PD-L1 therapies aims to further enhance anti-tumor activity.

We aim to identify subsets of patients most likely to respond to this treatment approach and to develop proof-of-concept clinical trials, with a focus on subsets of more common cancers and potentially orphan indications to facilitate a rapid path to registration and approval.

FS118 – F-star's LAG-3 and PD-L1 mAb² Bispecific Antibody



Our most advanced product candidate, FS118, aims to rescue checkpoint inhibitor treatment failures and is a mAb² bispecific antibody targeting two receptors, PD-L1 and LAG-3, both of which are established pivotal targets in immuno-oncology. We are currently conducting in a proof-of-concept Phase 2 trial for FS118 in PD-1/PD-L1 acquired resistance head and neck cancer patients. Phase 1 data demonstrated that FS118 is well tolerated with a disease control rate of 49 % in a heavily pretreated population and supports the testing of FS118 in cancers with acquired resistance to prior PD-1/PD-L1 inhibitors.

Inhibitory Roles of LAG-3 and PD-L1 in Immuno-oncology

PD-1 is a checkpoint inhibitor that is present on the surface of activated T cells and has a role in downregulating the immune system to help prevent an attack on healthy tissue. However, this inhibitory mechanism can also prevent the immune system from killing cancer cells. PD-L1, the ligand for PD-1, is expressed by a broad range of both tissues and immune cells. A wide range of tumors, including solid tumors, can upregulate PD-L1 in response to pro-inflammatory cytokines, such as interferon gamma. Engagement of PD-L1 with PD-1 on activated tumor infiltrating lymphocytes ("TILs"), can deliver inhibitory signals that protect the tumor from immune destruction.

LAG-3 is also a checkpoint inhibitor expressed on immune cells, including activated T cells. LAG-3 binds to a group of cell surface proteins known as major histocompatibility complex ("MHC"), class II molecules that are present on antigen presenting cells. MHC proteins are responsible for presenting foreign antigens to the immune system, after which the T cells are activated to attack and clear the foreign entity. When MHC class II molecules bind to LAG-3, this T cell activation is suppressed, which, under normal conditions, helps to prevent over activation of the immune system. In tumors, LAG-3 becomes overexpressed on TILs, thereby suppressing the T cell activation needed for an anti-tumor immune response. Accordingly, LAG-3 expression in TILs is generally associated with poor prognosis. A role for LAG-3 shedding in resistance to PD-1 blockade has been highlighted in a recent preclinical study showing that mice that are unable to shed LAG-3 from the surface of T cells are resistant to PD-1 therapy. A high level of LAG-3 and low levels of a disintegrin and metalloproteinase ("ADAM")-10, a metalloproteinase regulating LAG-3 shedding, on T cells from the blood of patients with head and neck cancer was also associated with a poor prognosis.

Potential Clinical Applications of a LAG-3/PD-L1 Bispecific Antibody

Therapeutic antibodies that reverse the immunosuppression of checkpoint inhibitors, thereby "releasing the brake" to allow the T cell to attack the tumor cell, have been clinically successful. Currently, several PD-1/PD-L1 antibodies are in development or have been approved by the FDA and other regulatory agencies in a variety of tumor types, including lung cancers, melanoma, renal cancers, bladder cancers, gastro-intestinal cancers, liver, head and neck and breast and cervical cancers. This cancer population represented over 10 million cases worldwide in 2020. Although long-lasting responses to PD-1/PD-L1 have been observed, the cancer ultimately becomes resistant, leaving a large, unserved patient population without effective treatment options, despite a portion of these patients expressing PD-1/PD-L1.

Emerging data suggest that LAG-3 upregulation may be a mechanism of resistance to PD-1 or PD-L1 therapy. A key observation is that therapeutic inhibition of the PD-1/PD-L1 checkpoint pathway leads to increased expression of LAG-3, which, in turn, may prevent responses to PD-1/PD-L1 therapy. Both LAG-3 and PD-1 become overexpressed on TILs in multiple preclinical tumor models and the combination of LAG-3 and PD-1 antibodies have demonstrated improvement of the anti-tumor response in murine models compared to blocking either one alone. The potential therapeutic benefit of the combination of traditional antibodies and bispecific antibodies targeting PD-1 and LAG-3 has been investigated in several clinical trials, and preliminary clinical results have indicated activity in PD-1/PD-L1 treatment naïve and resistant tumors.

Based on results generated using a combination of two traditional antibodies targeting PD-1 and LAG-3, and the observation that an increase in LAG-3 expression may contribute to resistance to PD-1 checkpoint therapy, we believe that a bispecific antibody that targets both PD-L1 and LAG-3 simultaneously, such as FS118, has broad potential as an immuno-oncology therapeutic. Simultaneous targeting of LAG-3 and PD-L1 with a bispecific antibody not only releases the brakes of two immunosuppressive pathways, but it may also have advantages over a combination of traditional antibodies by focusing these effects at PD-L1 positive sites in the tumor or by crosslinking between immune cells in the tumor microenvironment. Recently, LAG-3 shedding was found to correlate with responsiveness to PD-1 therapy in murine tumors and in the clinic high levels of LAG-3 and low levels of ADAM-10 correlated with a poor outcome of PD-1 treatment. Therefore, increased shedding of LAG-3 from the surface of the T cell, due to tetravalent bispecific-binding to LAG-3 and PD-L1, may result in lower LAG-3 levels in the tumor and potentially prevents one of the mechanisms of acquired resistance to PD-1/PD-L1 therapies.

Resistance to PD-1/PD-L1 regimens can come in two main forms. “Primary resistance” is where the cancer shows no sensitivity to treatment and continues to grow. “Acquired resistance” to PD-1/PD-L1 regimens, sometimes referred to as secondary resistance, is where there is initial sustained (greater than or equal to three months) clinical benefit (defined as a complete response, partial response, or stable disease) from therapy but the cancer then starts to grow again while the patient is still being treated. Our analysis of preliminary clinical data from the first-in-human study of FS118 indicates that FS118 may have greater clinical activity in patients with acquired resistance compared to primary resistance. While we have not assessed this, we also believe that FS118 will have clinical activity in cancer patients who have not previously been exposed to PD-1/PD-L1 therapy.

Tumor types with immuno-suppression or T cell exhaustion may co-express LAG-3 and PD-L1 and could benefit from treatment with our dual checkpoint inhibitor product candidate, FS118. Examples of such tumors include head and neck, soft-tissue sarcoma, mesothelioma, ovarian, gastric cancer, anaplastic thyroid cancer and small cell lung cancer. Globally, this cancer population represents over 2.5 million new diagnoses annually. Our focus will be on patients with cancers whose tumors co-express LAG-3 and PD-L1 and who have developed acquired resistance to PD-1/PD-L1 therapy or who have not yet received it.

Squamous cell carcinoma of the head and neck, otherwise known as head and neck cancer, includes cancers of the mouth (oral cavity, oral cancers, tongue) and throat (oropharynx and tonsils, nasopharynx and hypopharynx), as well as rarer cancers of the nasal cavity, sinuses, salivary glands and the middle ear. According to GLOBOCAN, in 2020 approximately 900,000 new head and neck cancer were estimated to have been diagnosed worldwide. Treatment of patients with advanced head and neck cancer consists of PD-1 therapy alone or in combination with chemotherapy in the first-line, in the metastatic setting. Approximately one-third of these patients develop Acquired Resistance to PD-1 therapy and, therefore, we plan to develop FS118 as a sequential treatment for these patients, either alone or in combination with standard of care therapies.

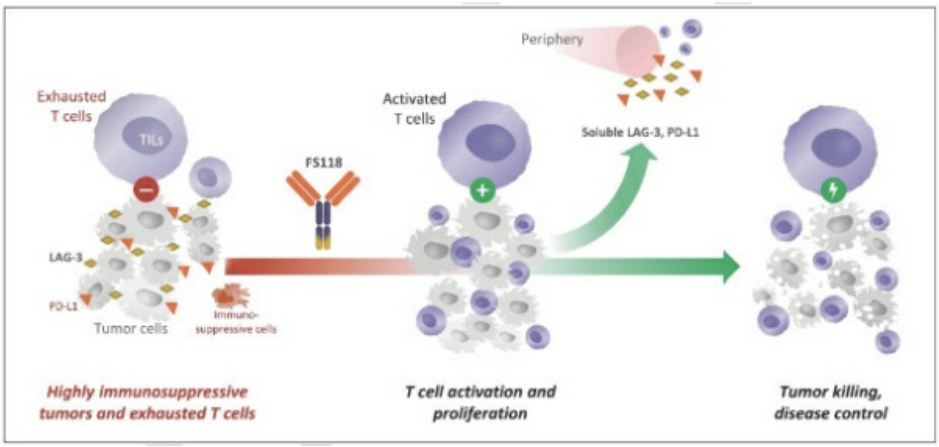
Malignant pleural mesothelioma (“MPM”) is a rare but aggressive cancer usually caused by asbestos exposure. According to GLOBOCAN, in 2020, it estimates up to approximately 25,000 new patients were diagnosed with MPM. For patients ineligible for surgery, which represents the large majority of this patient population, the first-line treatment consists of chemotherapy. Recently, published data from a randomized

Phase 3 trial comparing the current standard of care of chemotherapy to the combination of a PD-1 inhibitor and a CTLA-4 inhibitor defines a new standard of care therapy and an opportunity to investigate the efficacy of FS118 in acquired resistance patients.

F-star's Solution to PD-1/PD-L1 Resistance: FS118

FS118 is a mAb^2 bispecific antibody that can simultaneously bind to LAG-3 through its Fcab domain and PD-L1 via its Fv domain. FS118 has demonstrated the potential to provide clinical benefit through multiple mechanisms based on its tetravalency. These include: (1) blocking the PD-1/PD-L1 immunosuppressive pathway, (2) blocking the LAG-3/MHC class II molecules interactions and (3) crosslinking and potentially clustering PD-L1 and LAG-3 receptors, including between different cells.

Mechanism of Action of FS118



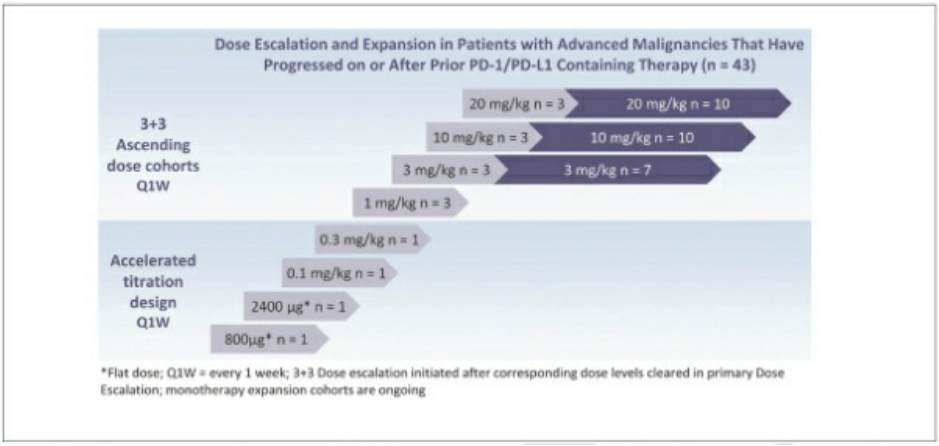
Our preclinical data demonstrated that FS118 has the potential to be more effective than a combination of PD-L1 and LAG-3 traditional antibodies. Moreover, these preclinical mice studies showed that administration of the mAb^2 bispecific antibody led to a downregulation of LAG-3 expression levels on T cells within the tumor, with an increase in serum soluble LAG-3, which we believe is due to receptor clustering, and is indicative of the strong pharmacology enabled by tetravalent bispecific binding. We believe this an important mechanism for potent disease control.

Phase 1 Clinical Trial

We have conducted a first-in-human Phase 1, open-label, dose-escalation clinical trial of FS118 in patients with advanced malignancies that have progressed on or after PD-1/PD-L1 checkpoint therapy for whom either no effective standard therapy is available or standard therapy has failed. The tumor types enrolled in this trial include sarcomas, lung cancers, mesothelioma, bladder cancers, ovarian cancers, prostate cancers, melanoma, mesothelioma, head and neck cancers, cervical cancers and thyroid cancers. Patients were heavily pretreated, including surgical procedures, chemotherapy or radiation therapy, and with a median of six prior lines of therapy. In addition, patients were required to have received prior treatment with a PD-1/PD-L1 containing regimen for a minimum of 12 weeks and subsequently shown disease progression. This patient population derives infrequent benefits from any further PD-1 therapy, and disease worsening may occur within eight weeks without an effective therapy.

Under the protocol, as depicted below, 43 patients received FS118 administered intravenously once weekly in three weekly cycles until disease progression. The initial cohorts were enrolled sequentially in single-patient dose escalation cohorts. Because no dose limiting toxicities were observed, further dose escalation up to 20 mg/kg proceeded in a 3+3 design associated with cohort extension to obtain more PK/PD data. The primary endpoints of this trial are safety, tolerability and pharmacokinetics. Secondary endpoints include disease control, as measured by RECIST 1.1 and iRECIST.

FS118 Phase 1 Clinical Trial Design



A total of 43 patients were enrolled in this trial at dose levels up to 20 mg/kg and data from this trial demonstrated that weekly administration of FS118 was well-tolerated and did not result in dose- or treatment-limiting toxicities and a maximum tolerated dose was not reached. No safety signals unexpected for the drug class of immune-checkpoint inhibitors were identified. The majority (95%) of treatment-emergent adverse events (“TEAE”), considered by the scientific review committee to be treatment-related were mild to moderate in severity (Grade 1 and 2). FS118-related grade 3 toxicities (liver enzyme increases) were observed in two patients (5%). No deaths were attributed to FS118 treatment. A recommended dose for Phase 2 trials (“RP2D”) was determined to be 10 mg/kg weekly. A disease control rate (“DCR”) of 49% in 39 evaluable patients was observed. In six of these patients, long term disease control (greater than six months) was observed, and it was noted that all of these patients had acquired resistance to their previous PD-1 or PD-L1 therapy. In acquired resistance patients, DCR was 59% (16 out of 27 patients) with a DCR at six months of 22.2% (six out of 27 patients). Low titers of anti-drug antibodies (“ADA”) were observed in 42% of patients. At the RP2D, ADAs were transient in nature and no effect on exposure was observed. Pharmacodynamic exposure was maintained across the dosing interval, as measured by an increase in soluble LAG-3. An increase in peripheral T cells was also observed following dosing.

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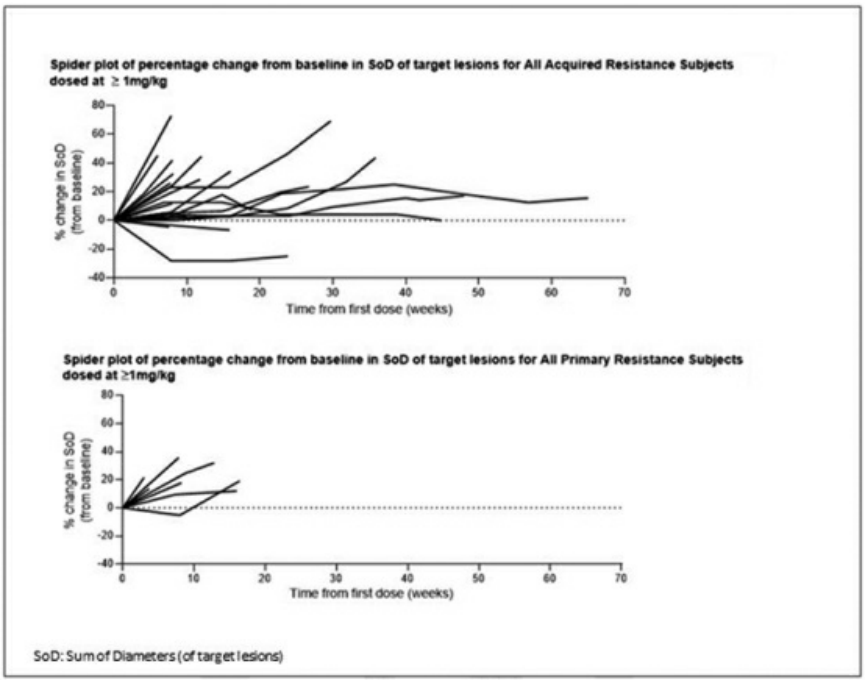
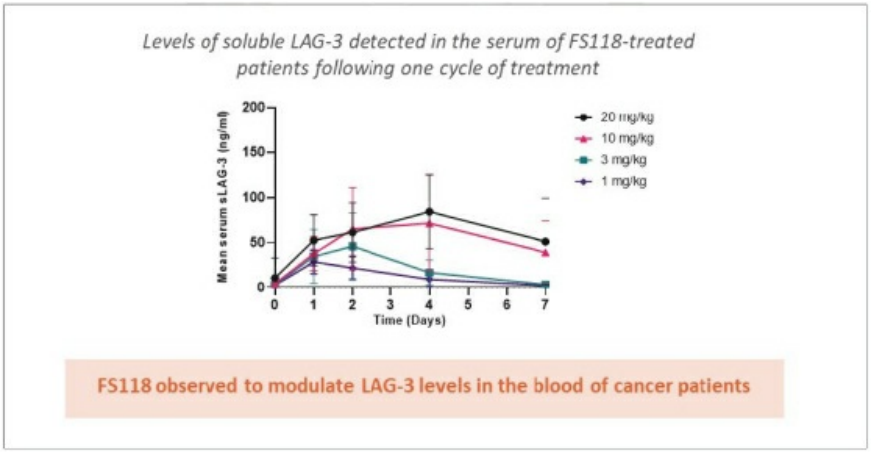
FS118 Phase 1 Clinical Trial Data





Clinical Development Strategy

The FS118 first-in-human clinical study data support further clinical investigations for monotherapy FS118 in cancers with acquired resistance. Initial clinical trials will take place in the second/third line metastatic setting.

In order to identify patients who, gain more benefit from FS118 therapy, we plan to investigate a number of biomarkers. Rational combinations with other anti-cancer therapies are also being considered for patients who are pre-treated with, or naïve to, PD-1/PD-L1 therapy.

We initiated a focused monotherapy proof-of-concept Phase 2 trial in selected head and neck cancers with acquired resistance in early 2021. Squamous Cell Carcinoma of Head and Neck was chosen for the proof-of-concept study based on both the existence of the targeted population of acquired resistance following the approval of an PD-1 inhibitor and the expression of both PD-L1 and LAG-3 in this patient set. If the study meets its primary objective of efficacy in LAG-3+/PD-L1+ patients, additional clinical studies in head and neck cancer will follow, assessing FS118 alone or in combination with other tumor targeting antibodies or chemotherapeutic agents. A Phase 3 registration clinical study would subsequently be conducted.

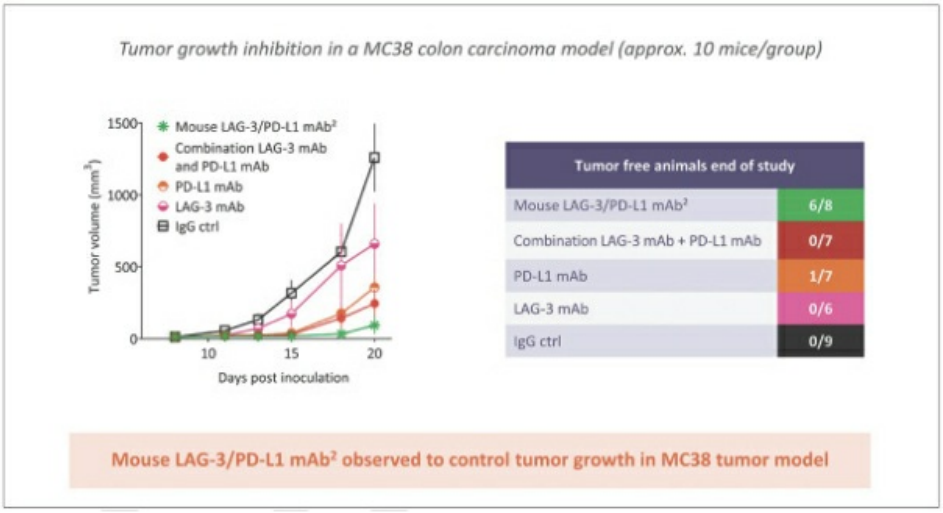
Other tumor types of interest that co-express PD-L1 and LAG-3, such as small cell lung cancer, ovarian cancer, mesothelioma and anaplastic thyroid tumors will be investigated in a “basket” or “platform” clinical trial. This is designed to facilitate multiple clinical efficacy signals with FS118 therapy in these tumor types and has the potential to apply biomarker patient selection strategies to enrich for efficacy and provides opportunity for accelerated approval.

If these trials are successful, we intend to seek marketing approval from the FDA, the EMA and other comparable regulatory bodies.

Preclinical Data

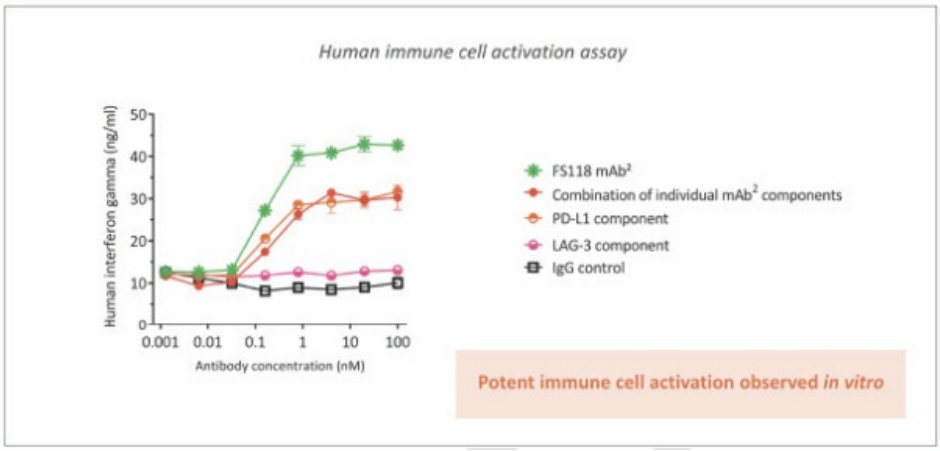
Superior anti-tumor activity observed compared to a combination of traditional antibodies

In order to explore the biology of FS118 in mice, we created a mouse mAb 2 bispecific antibody equivalent of FS118 (mouse LAG-3/PD-L1 mAb2) and tested its ability to control tumor growth in an established immuno-oncology preclinical mouse model (MC38). In this preclinical model, FS118 effectively reduced tumor growth and was observed to be more potent than the combination of a PD-L1 and a LAG-3 antibody, as demonstrated by the number of tumor-free animals at the end of the preclinical study.



FS118 observed to be a potent activator of T cells in a human cell-based assay

The ability of FS118 to activate human T cells was tested *in vitro* using immune cells from human blood, as detected by increased interferon gamma release. FS118, which is designed to bind to and crosslink both LAG-3 and PD-L1, was more potent than the combination of the individual bispecific components, suggesting that the tetravalent binding and crosslinking of FS118 led to enhanced immune cell activation.



FS118 observed to induce shedding of LAG-3 in human ex vivo T cells

In an *in vitro* T cell activation assay with immune cells expressing PD-L1, it was observed that FS118 increased the concentration of soluble LAG-3 detected in the cell culture medium. This increase in soluble LAG-3 was not observed with the combination of the individual bispecific components, demonstrating a potentially differentiated bispecific antibody mechanism of action for FS118 where LAG-3 shedding requires simultaneous binding to both PD-L1 and LAG-3. Furthermore, FS118-mediated shedding was dependent upon ADAM-10 and ADAM-17 metalloproteinases, indicating that LAG-3 is enzymatically cleaved from the cell surface. An increase in soluble LAG-3 in the blood was observed in a mouse tumor model upon dosing with a mouse LAG-3/PD-L1 mAb².

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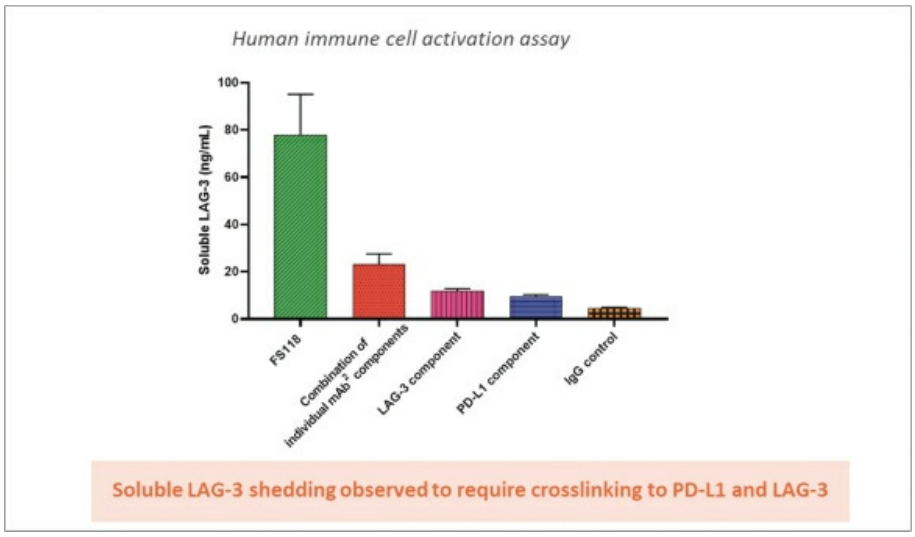
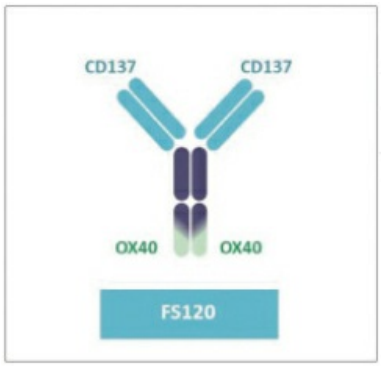


FS120 – F-star's OX40 and CD137 mAb² Bispecific Antibody



FS120 aims to improve checkpoint inhibitor and chemotherapy outcomes and is a mAb² bispecific antibody that is designed to bind to and stimulate OX40 and CD137, two proteins found on the surface of T cells that both function to enhance T cell activity. We are developing FS120 alone and in combination with PD-1/PD-L1 therapy for the treatment of tumors where PD-1/PD-L1 products are approved and which have co-expression of OX40 and CD137 in the tumor microenvironment, such as gastric and bladder cancer. We initiated a Phase 1 clinical trial in patients with advanced cancers in the fourth quarter of 2020.

Stimulatory Roles of OX40 and CD137 in Immuno-oncology

The biological basis for primary and acquired resistance to current checkpoint therapies has been widely explored, resulting in the identification of many contributory factors. Key among these factors are the number of TILs and the number of mutations in the tumor cells, which is known as the tumor mutational burden ("TMB"). Tumors with low levels of TILs, referred to as "cold" tumors, are less responsive or non-responsive to current therapies.

One approach to increase the number and level of activation of TILs is by broad stimulation of the immune system via costimulatory regulators. Preclinical studies showed that the anti-tumor efficacy of therapeutic tumor targeting antibodies can be augmented by the addition of antibodies targeting costimulatory molecules, such as CD137 and OX40.

When TILs first become activated, they upregulate OX40 and CD137 which are members of the tumor necrosis factor receptor superfamily. Further activation can be achieved by stimulation of OX40 and CD137. OX40 stimulation promotes T cell proliferation and survival and decreases the activity of immuno-suppressive T cells to further amplify the immune activation. Moreover, it preserves cellular memory for a more durable response and facilitates migration to other tumor sites. CD137 is expressed on multiple cell types including T cells and natural killer ("NK cells"). CD137 stimulation on T cells helps to mount an effective immune response by enhancing T cell proliferation and survival. Both the OX40 and CD137 activation pathway requires receptor clustering of the respective molecules on cells that triggers a signaling cascade resulting in enhanced immune response and thereby, tumor cell killing.

Potential Clinical Applications of an OX40/CD137 Bispecific Antibody

OX40 and CD137 agonist antibodies can "hit the gas" (immune stimulation) and have been shown to be effective immunotherapeutic agents across preclinical cancer models. Traditional OX40 antibodies have been extensively studied in the clinic as monotherapies. In addition, OX40 antibodies have been studied in combination with PD-1/PD-L1 and CTLA-4 antibodies and chemotherapy. Other programs are exploring a triple combination approach with PD-L1, CD137 and OX40 antibodies.

Monotherapy with traditional CD137 antibodies has not restored immune control of cancer in the majority of patients tested in clinical trials. In the case of the two most advanced traditional CD137 antibodies in clinical trials, doses tested have either demonstrated early efficacy but have been limited by severe liver toxicity or have been well-tolerated but have not demonstrated anti-cancer efficacy even at the highest doses tested. Both of these traditional CD137 antibodies are being tested in combination with PD-1/PD-L1 antibodies and other agents to potentially improve efficacy.

OX40 activation predominantly stimulates $CD4^+$ T cells, called helper T cells, whereas CD137 stimulates $CD8^+$ T cells, called killer T cells. We believe a bispecific antibody that "hits the gas" simultaneously through OX40 and CD137, such as FS120, will be able to concentrate these different immune cell subsets in the tumor, increasing activity of both helper and killer T cells. In addition, we believe this targeted stimulation of the immune system will increase the number of activated TILs in the tumors. Both mechanisms lead to stronger anti-tumor activity and increased therapeutic benefit as compared to traditional antibodies. Using a bispecific dual agonist for broad stimulation could also be combined with checkpoint inhibitors, including PD-1 and PD-L1.

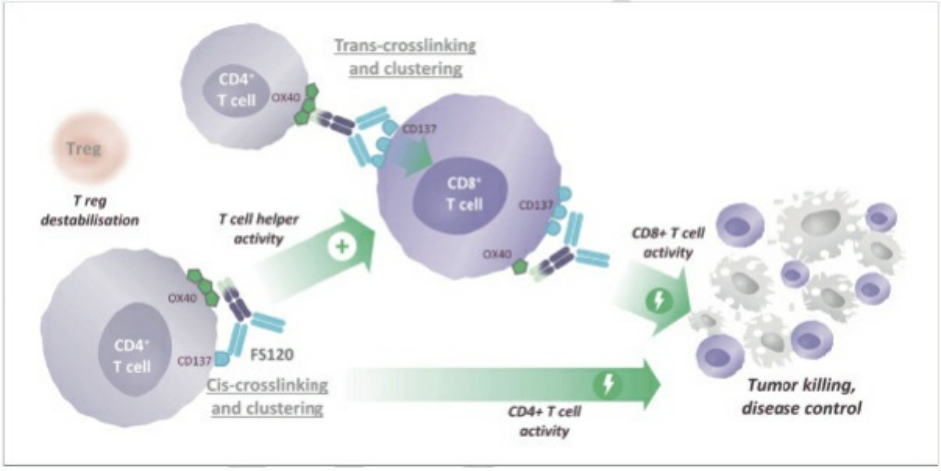
We believe that our preclinical data support FS120 being developed in combination with PD-1/PD-L1 therapy or chemotherapy. This approach may broaden the application of PD-1/PD-L1 therapy to tumor types or sub-populations that respond poorly to PD-1/PD-L1 therapy because they are likely to have TILs expressing both CD137 and OX40. Conversely, a PD-1/PD-L1 and FS120 combination may deepen clinical responses and prolong clinical benefit in patients who already gain benefit from PD-1/PD-L1 therapy. In order to select tumor types of interest, we analyzed gene expression data from solid tumors and found highly correlated expression levels of both OX40 and CD137 in several cancers where PD-1/PD-L1 therapy is approved including, but not limited to, bladder, head and neck, small and non-small cell lung cancers.

Bladder cancer was diagnosed in over 500,000 patients globally in 2020. PD-1 therapy is approved for use in the first line setting in patients who are not eligible for standard chemotherapy and who have high levels of PD-L1. We plan to explore PD-1 in combination with FS120 in bladder cancer patients with varying levels of PD-L1. Head and neck cancer affects over 900,000 patients world-wide every year. Therapy with PD-1 regimens is approved as a treatment in the first line setting. However, clinical outcomes remain suboptimal across PD-L1 levels and we believe there is an opportunity to bolster PD-1 clinical activity through combining with FS120 in first-line treatment.

F-star Solution: FS120

FS120 is a mAb^2 bispecific antibody that binds to OX40 through its Fcab domain, and CD137 via the Fv domain. FS120 is a dual costimulatory antibody or agonist that "hits the gas" on immune activation by activating both CD137 and OX40. We believe the tetravalent binding of FS120 differentiates it from current therapeutic approaches being developed in the clinic, because FS120 is designed to lead to enhanced clustering and potent and conditional stimulation between T cells (*trans*) and potentially on the same cell (*cis*).

Mechanism of Action of FS120



Our preclinical studies have shown superior anti-tumor activity of a mouse OX40/CD137 mAb ^{2} compared to a combination of two traditional antibodies. Based on the results, we believe FS120 may deliver clinical benefit through mechanisms arising from dual stimulation. These include: (1) activation of TILs in tumors to help overcome checkpoint inhibitory signals, which we believe will improve the response rates to PD-1/PD-L1 inhibitors and (2) increasing the number and persistence of CD4$^+$ (helper) and CD8$^+$ (killer) T cells and destabilizing T regulatory cells, which has the potential to reduce the risk of relapse for patients treated with the standard of care.

Traditional CD137 antibodies have Fc domains that lead to crosslinking using Fc gamma receptors that are widely expressed in the body, which are believed to result in off-tumor activation and subsequent hepato-toxicities. Accordingly, we designed FS120 with specific mutations that alter the binding of the Fc domain to Fc gamma receptors to prevent the killing of the immune cells by ADCC and to make FS120 activity independent of Fc gamma receptors, which we believe is important for efficacy and safety benefits. Both OX40 and CD137 are found highly expressed in TILs versus blood. Therefore, we believe this will make FS120 immune activation conditional within cancer tissue, limit potential systemic toxicities and lead to safety benefits.

Clinical Plans

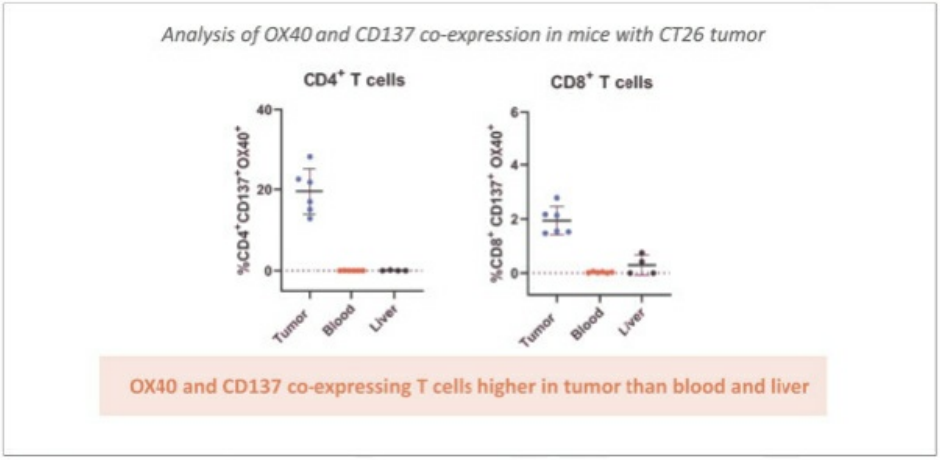
We initiated a Phase 1 open-label, dose-escalation clinical trial of FS120 in patients with advanced cancers in the fourth quarter of 2020. If we are able to establish a preliminary safety profile of FS120 in the dose-escalation phase of this trial, we will investigate its clinical activity in patients with cancers that co-express OX40

and CD137. Further, we intend to explore FS120 in combination with PD-1 therapy focusing on selected tumor types. In the future, FS120 may also be explored in combination with chemotherapy. The initial safety and proof-of-concept efficacy studies in selected tumor types will be conducted within the Phase 1 protocol. This approach could potentially support expedited regulatory approval and/or the initiation of Phase 3 registrational trials.

Preclinical Data

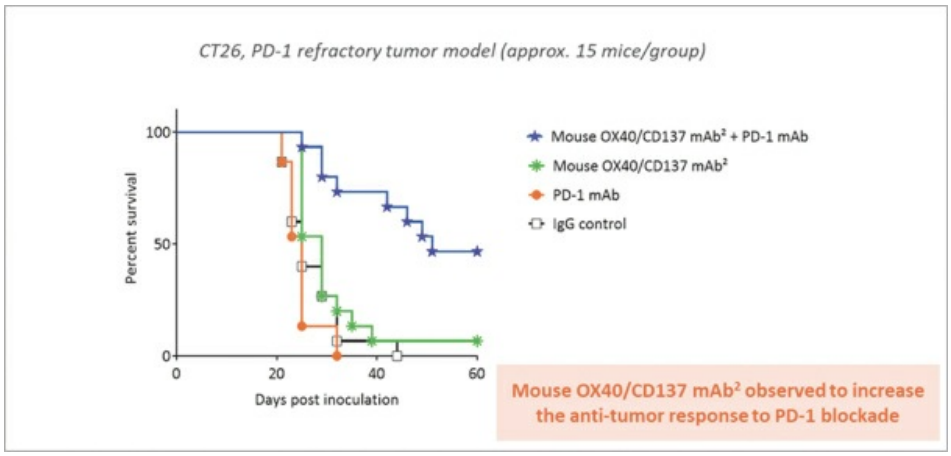
Co-expression of OX40 and CD137

In an established preclinical mouse tumor model (CT26), we analyzed the number of immune cells that co-expressed OX40 and CD137 in the tumor, blood and in the liver. We observed that a high number of T cells in the tumor co-expressed OX40 and CD137, whereas T cells in peripheral blood and liver did not co-express OX40 and CD137. Co-expression of OX40 and CD137 has also been observed in human tumors including non-small-cell lung cancer. The higher number of co-expressing T cells in the tumor suggests that the activity of FS120 should be highly active at the tumor site, in comparison to non-specific activation of immune cells throughout the body, potentially providing a safety benefit.



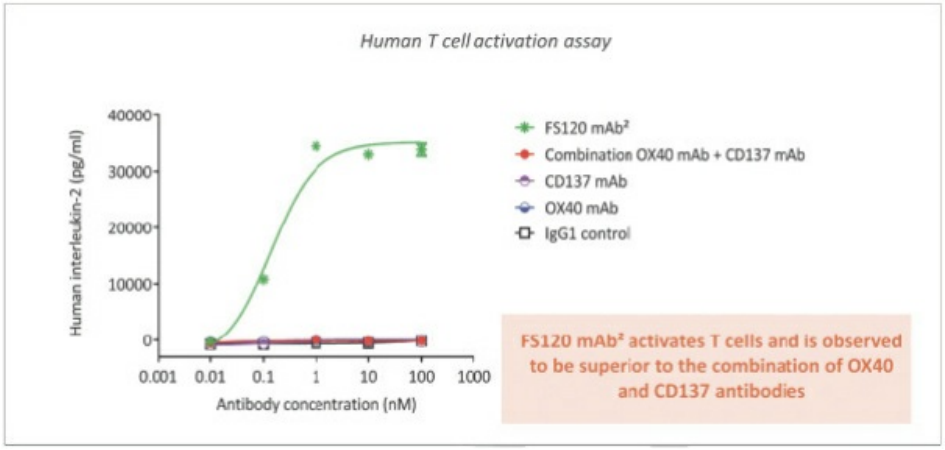
Enhanced anti-tumor response to PD-1 blockade observed

We observed a significant reduction in tumor growth in an established preclinical mouse tumor model (CT26) in a treatment with a mouse mAb[2] bispecific antibody equivalent of FS120, referred to as the mouse OX40/CD137 mAb [2]. When the mouse OX40/CD137 mAb [2] was used in combination with a PD-1 antibody, we observed increased long-term survival compared to what was observed with the monotherapy of either PD-1 or the mouse OX40/CD137 mAb [2].



FS120 was observed to be superior to antibody combinations in activating human T cells

Human immune cells can be activated *in vitro* to upregulate OX40. Addition of FS120 to these cells resulted in enhanced stimulation of human T cells, as detected by increased interleukin-2 expression. The combination of CD137 and OX40 traditional antibodies was observed to be ineffective in this assay. We believe that, in contrast to the traditional antibodies, FS120's observed potent activity is due to its ability to activate T cells independent of Fc gamma receptors.

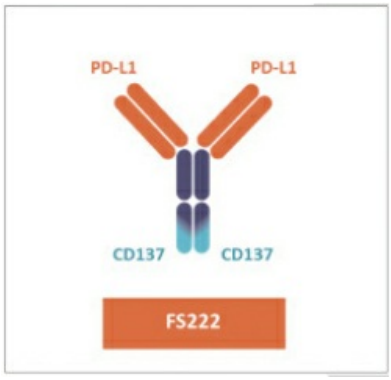


FS120 was observed to be well-tolerated in preclinical studies

In an IND-enabling toxicology study conducted in non-human primates, FS120 was observed to be well-tolerated at doses up to the maximum administered dose of 30 mg/kg. No adverse observations, including no acute increases in serum cytokines levels were reported. This was consistent with our results from cytokine

release assays performed using human blood. The non-human primate study also showed dose-dependent increases in proliferating $CD4^+$ (helper), $CD8^+$ (killer) T cells and NK cells, consistent with our findings in murine pharmacology studies using the OX40/CD137 mAb^2 surrogate.

FS222 – F-star's CD137 and PD-L1 mAb^2 Bispecific Antibody



FS222 aims to improve outcomes in low PD-L1 expressing tumors and is a mAb^2 bispecific antibody that is designed to target both the costimulatory CD137 and the inhibitory PD-L1 receptors, which are co-expressed in a number of tumor types including non-small-cell lung cancer, ovarian cancer and gastrointestinal cancers such as colorectal and esophageal cancer. FS222 is aimed at improving outcomes in PD-L1 low tumors. We initiated a Phase 1 clinical trial in patients with advanced cancers for FS222 in late 2020. We believe there is a strong rationale to combine FS222 with other anti-cancer agents, including targeted therapy and chemotherapy, and this can be done within the Phase 1 study.

Potential Clinical Applications of a CD137/PD-L1 Bispecific Antibody

A CD137 and PD-L1 bispecific antibody has the potential to increase the efficacy compared to the combination of two traditional antibodies. Both targets are present on tumor and immune cells within the tumor environment. Blocking the PD-L1 pathway acts to "release the brake" thereby reducing immunosuppression, while stimulating the CD137 pathway acts to "hit the gas" and amplify immune activation. CD137-driven T cell activation results in interferon gamma cytokine release. This cytokine release causes increases in PD-L1 on tumor and immune cells. We believe that this upregulation of PD-L1 could be a resistance mechanism of traditional CD137 antibody therapy that limits its activity in the tumor microenvironment.

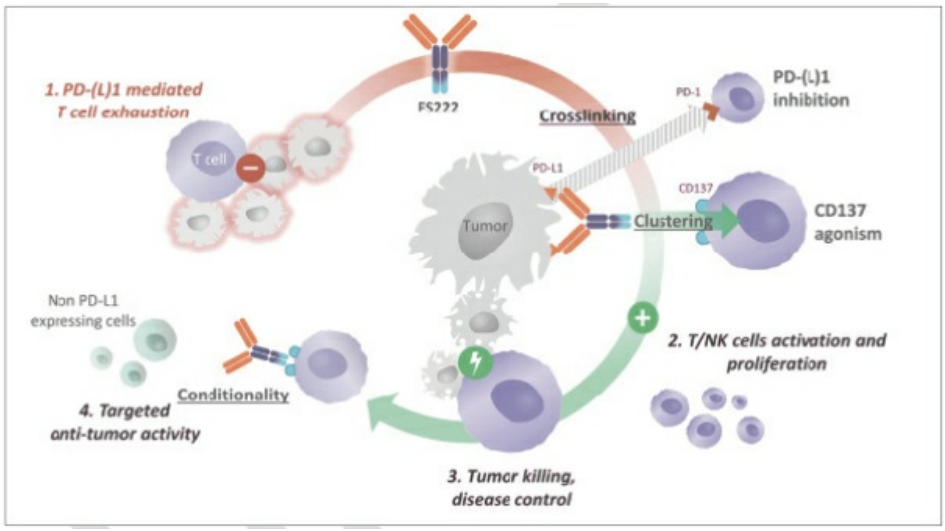
We intend to develop FS222 in cancers that co-express both CD137 and PD-L1 receptors. Tumors such as non-small-cell lung cancer, ovarian cancer, colorectal cancer, esophageal and cancers positive for tertiary lymphoid structures (TLS+) are likely to have tumor-resident T cells and NK cells expressing CD137, as well as cells that express PD-L1. These represent tumor types that individually and collectively have a spectrum of PD-L1 expression from high to low (less than 5% cells that express PD-L1). These cancer types are diagnosed in over 4.6 million patients globally every year and represent attractive indications for FS222. We plan to focus on defined clinical segments of these cancers. For example, there is need for sequential treatments after failure on PD-1/PD-L1 regimens in non-small-cell lung cancer, which are currently given in the first line setting or after failure on targeted agents. We believe there is a broad opportunity for FS222, either alone or in combination with other anti-cancer therapies, in treating these patient populations.

F-star's Solution: FS222

FS222 is a mAb^2 bispecific antibody that binds to CD137 through its Fcab domain and PD-L1 via the Fv domain. FS222 simultaneously "releases the brake" on immune control of cancer by blocking the PD-1/PD-L1 pathway and "hits the gas" on immune activation by activating the CD137 pathway. FS222 has the potential to provide clinical benefit through multiple mechanisms based on its tetravalency. These include: (1) blocking the PD-1/PD-L1 immunosuppressive pathway and (2) conditionally clustering and crosslinking CD137 receptors, resulting in activation of CD137 in a PD-L1-dependent manner. We believe this dual mechanism of action would

amplify the anti-tumor activity of FS222. Our preclinical data shows that FS222 has the potential to be more effective than a combination of traditional PD-L1 and CD137 antibodies, as well as applicability in PD-L1 low tumors, a significant area of unmet medical need.

Mechanism of Action of FS222



Similar to FS120, FS222 has been designed with specific mutations to make its activity independent of binding to Fc gamma receptors. PD-L1 is frequently expressed at high levels on cells within cancer tissue compared to non-cancer tissue. Therefore, we believe this will make FS222 immune activation conditional within cancer tissue, limit potential systemic toxicities and lead to safety benefits.

Clinical Plans

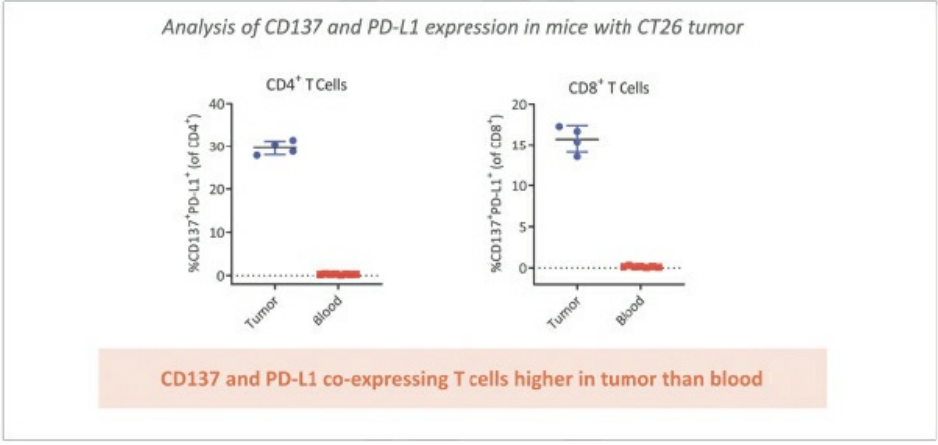
We initiated a Phase 1 open-label, dose-escalation clinical trial of FS222 in patients with advanced cancers in late 2020. The initial safety and proof-of-concept efficacy studies in selected tumor types will be conducted within the Phase 1 protocol. While we attempt to establish the preliminary safety and optimal dosing regimen for FS222, we will simultaneously investigate preliminary efficacy signals with FS222 therapy in a small number of tumor types of interest, potentially including colorectal, non-small-cell lung cancer, esophageal, ovarian and TLS+ tumors. These data will form the basis for the selection of specific tumor types in which to assess the clinical activity of FS222 in a larger group of patients in the Phase 1 study. This approach could potentially support expedited regulatory approval and/or the initiation of Phase 3 registrational trials.

Preclinical Data

Co-expression of CD137 and PD-L1

In an established preclinical mouse tumor model (CT26), we analyzed the percentage of immune cells that co-expressed CD137 and PD-L1, both in the tumor and in the blood. We observed that a high number of T cells in the tumor co-expressed CD137 and PD-L1, whereas T cells in peripheral blood did not co-express CD137 and

PD-L1. Co-expression of CD137 and PD-L1 has also been observed in human tumors including non-small-cell lung cancer. The higher number of co-expressing T cells in the tumor suggests that the activity of FS222 should be highly active at the tumor site, in comparison to non-specific activation of immune cells throughout the body, potentially providing a safety benefit. In an IND/CTA-enabling toxicology study conducted in non-human primates, FS222 was observed to be well-tolerated at doses up to the maximum administered dose of 30 mg/kg. No adverse observations, including no acute increases in serum cytokines levels were reported. This was consistent with our results from cytokine release assays performed using human blood. The non-human primate study also showed dose-dependent increases in proliferating $CD4^+$ (helper), $CD8^+$ (killer) T cells and NK cells, consistent with our findings in murine pharmacology studies using the CD137/PD-L1 mAb^2 surrogate.



Superior anti-tumor activity observed compared to a combination of traditional antibodies

In an established preclinical mouse tumor model (MC38), treatment with a mouse mAb^2 bispecific antibody equivalent of FS222 (mouse CD137/PD-L1 mAb^2) was observed to lead to long-term survival and complete tumor elimination in all treated mice, an effect that was observed to be unmatched by two traditional antibodies in combination. We believe this effect was observed because of FS222's ability to deliver the dual anti-cancer mechanisms.

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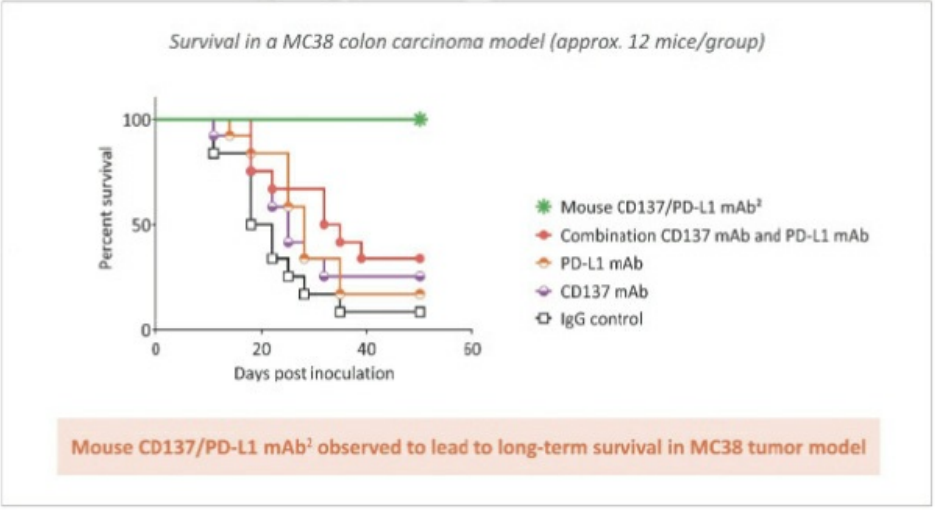
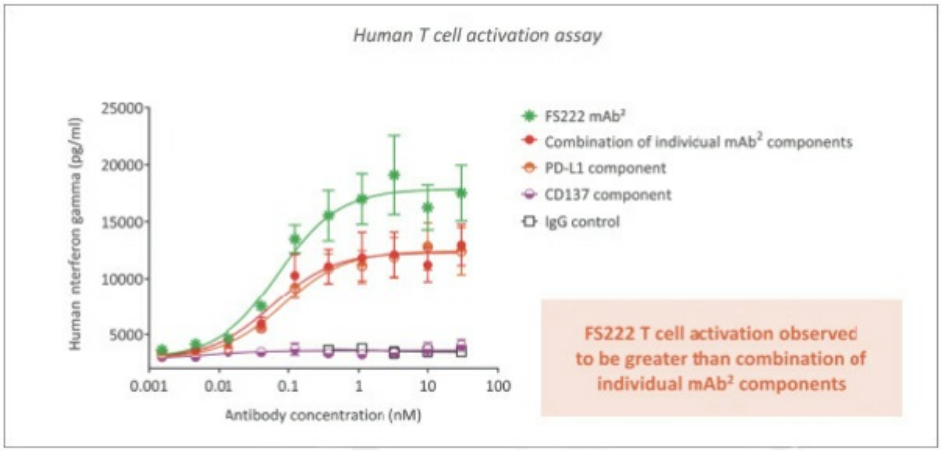


FS222 observed to be a potent activator of human T cells

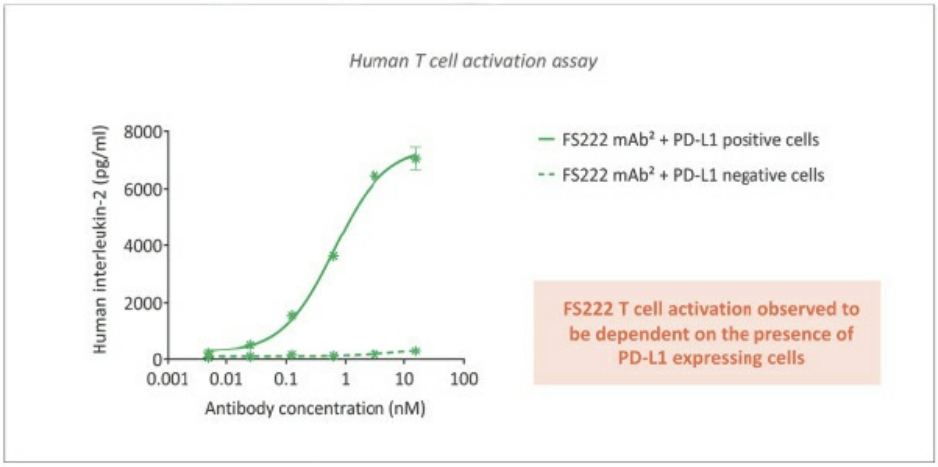
The ability of FS222 to activate T cells isolated from human blood was tested *in vitro*. FS222 was observed to be a potent activator of human T cells, as detected by increased interferon gamma release. FS222 was more potent than the combination of its individual bispecific components, indicating that FS222's tetravalent binding and crosslinking led to enhanced T cell activation.



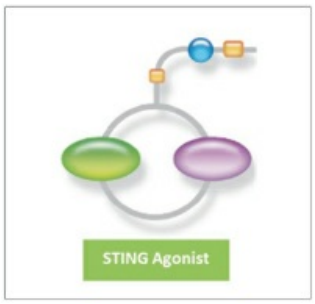
FS222-induced T cell activation was observed to be dependent on PD-L1

We tested whether FS222's T cell activation was dependent on PD-L1 binding and therefore, conditional. In an *in vitro* assay with human T cells and other cells expressing PD-L1, we observed that FS222 activation of T

cells required binding to PD-L1 and importantly could be demonstrated with lower levels of PD-L1. This demonstrated that FS222 required binding to both CD137 and PD-L1 to crosslink and cluster CD137 and conditionally activate the T cells. As anticipated, in addition to inducing CD137 activation, FS222 also blocked the PD-1/PD-L1 pathway, which we have demonstrated *in vitro*.



SB 11285 – F-star's STING Agonist



SB 11285 is a next generation cyclic dinucleotide STING agonist designed to improve checkpoint inhibition outcomes as an immunotherapeutic compound for the treatment of selected cancers. We are conducting an open-label, dose-escalation Phase 1 clinical trial with SB 11285 as an IV administered monotherapy, and in combination with an anti-PD-L1 antibody, in patients with advanced solid tumors.

Potential Clinical Application of STING Agonist

The induction of interferons and interferon-stimulated genes in tumor cells and within the tumor microenvironment has been shown to modulate the host-immune response and induce apoptosis of tumor cells. Activation of the STING pathway can result in the induction of cellular interferons including interferon-b and other cytokines while promoting a strong anti-tumor response through the induction of innate and adaptive immune responses. Therapeutically targeting the STING pathway could turn an immunologically "cold" tumor into a "hot" one, making it more likely to respond to other forms of immunotherapy, such as immune checkpoint inhibitors.

The cyclic GMP-AMP synthase (cGAS)–STING pathway is involved in the innate immune response against the tumor. Upon detection of cytosolic tumor-derived DNA, cGAS generates cyclic dinucleotides that bind

STING, leading to the release of Type-I interferon and proinflammatory cytokines, ultimately promoting T cell priming and recruitment. STING also regulates anticancer immunity in a Type I interferon-independent manner by inducing cell death and facilitating the release of cancer cell antigens. Multiple STING agonists are being investigated in clinical trials, but many exhibit poor metabolic stability and were delivered intratumorally. A STING agonist that can be administered intravenously (IV) has the potential to target advanced metastatic tumors such as melanoma and head and neck carcinomas.

Squamous cell carcinoma of the head and neck, otherwise known as head and neck cancer, includes cancers of the mouth (oral cavity, oral cancers, tongue) and throat (oropharynx and tonsils, nasopharynx and hypopharynx), as well as rarer cancers of the nasal cavity, sinuses, salivary glands and the middle ear. According to GLOBOCAN, in 2020 approximately 900,000 new head and neck cancer were estimated to have been diagnosed worldwide.

The approval of the check point inhibitor pembrolizumab as a monotherapy or in combination with chemotherapy represents an opportunity for the STING agonist to improve upon the efficacy of PD-1/PD-L1 inhibitors and offer to the patients a chemotherapy free option.

F-star's Solution: STING Agonist

We are developing our STING agonist product candidate, SB 11285, as a next-generation immunotherapeutic synthetic cyclic dinucleotide for the treatment of selected cancers. In preclinical studies in multiple tumor-derived cell lines, SB 11285 induced the release of cytokines consistent with engagement of the STING target, as well as cell death and apoptosis. Based on the preclinical studies performed to date, SB 11285 has demonstrated efficacy in multiple rodent tumor models when administered intravenously or intratumorally. We believe that SB 11285 may be administered clinically by multiple routes of administration, enabling SB 11285 to target a variety of tumors at various anatomic sites. Furthermore, SB 11285 has the potential to be used in combination with other therapeutic modalities to enhance efficacy. Following the administration of SB 11285 in a preclinical tumor model, there was upregulation of the PD-1 molecule, which we believe underscores the potential utility of its approach to employ the activity of a PD-1/PD-L1 checkpoint inhibitor.

Ongoing Phase 1 Clinical Trial and Clinical Development Strategy

SB 11285 is currently being evaluated as an IV-administered monotherapy in a Phase 1 multicenter, dose escalation clinical trial in patients with advanced solid tumors. Part 1a of this trial is a dose-escalation study with IV SB 11285 monotherapy and part 1b is a dose escalation of SB11285 combined with a fixed and therapeutic dose of an anti-PD-L1 antibody. Roche's PD-L1 checkpoint inhibitor atezolizumab (Tecentriq®) is being used. This trial is designed to determine a recommended Phase 2 dose for both the monotherapy and combination with atezolizumab.

The objectives of the Phase 1 clinical trial include determining a safe and pharmacodynamically active dose of IV-administered SB 11285 and preliminary assessment of antitumor activity. The Phase 1 dose escalation study was designed to evaluate ascending doses of SB 11285 with respect to dose-limiting toxicities, maximum tolerated dose, and to determine a recommended Phase 2 dose as well as the pharmacokinetic/pharmacodynamic profile as monotherapy and in combination with atezolizumab. Following the completion of the part 1a/1b portion of the trial, part 2 of the trial is designed to explore the antitumor activity of SB11285 in combination with atezolizumab in pre-specified tumor types such as head and neck cancer and melanoma.

The Phase 1 trial was initiated in the fourth quarter of 2019 and we expect to report an update on the trial in mid-2021.

Collaborations and License Agreements

We have entered several collaborations with an aim to discover and develop novel drug candidates across a variety of clinical indications.

2016 License and Collaboration Agreement with Denali Therapeutics Inc.

In August 2016, F-star Biotechnology Limited, F-star Gamma Limited ("F-star Gamma"), and F-star Biotechnologische Forchungs-und Entwicklungsges.m.b.H entered into a license and collaboration agreement (the "Denali License and Collaboration Agreement"), with Denali Therapeutics Inc. ("Denali"). The goal of the collaboration was the development of certain constant Fc domains of an antibody with non-native antigen binding activity ("Fcabs"), to enhance delivery of therapeutics across the blood brain barrier into the brain. The collaboration was designed to leverage our modular antibody technology and Denali's expertise in the development of therapies for neurodegenerative diseases. In connection with the entry into the collaboration agreement, Denali also purchased from the F-star Gamma shareholders an option, which we refer to as the buy-out-option, to acquire all of the outstanding shares of F-star Gamma pursuant to a pre-negotiated share purchase agreement.

On May 30, 2018, Denali exercised the buy-out option and entered into a Share Purchase Agreement (the "Purchase Agreement"), with the shareholders of F-star Gamma and Shareholder Representative Services LLC, pursuant to which Denali acquired all of the outstanding shares of F-star Gamma (the "Acquisition").

As a result of the Acquisition, F-star Gamma has become a wholly owned subsidiary of Denali and Denali changed the entity's name to Denali BBB Holding Limited. In addition, Denali became a direct licensee of certain of our intellectual property (by way of Denali's assumption of F-star Gamma's license agreement with us (the "F-star Gamma License")). Denali made initial exercise payments to us and the former shareholders of F-star Gamma under the Purchase Agreement and the F-star Gamma License in the aggregate, of $18.0 million, less the net liabilities of F-star Gamma, which were approximately $0.2 million. Of this total, $4.0 million was payable to us. In June 2019, Denali made a payment of $1.5 million to us upon achieving a GMP Manufacturing milestone. In addition, Denali is required to make future contingent payments, to us and the former shareholders of F-star Gamma, with a maximum aggregate value of $437.0 million upon the achievement of certain defined preclinical, clinical, regulatory and commercial milestones. Of this total, a maximum of $91.4 million is payable to us. The total amount of the contingent payments varies depending on whether a milestone is triggered by a molecule that incorporates an Fcab that has been developed solely by us or developed solely by Denali.

Under the terms of the Denali License and Collaboration Agreement, Denali had the right to nominate up to three Fcab targets ("Accepted Fcab Targets"), within the first three years of the date of the Denali License and Collaboration Agreement. Upon entering into the Denali License and Collaboration Agreement, Denali had selected transferrin receptor ("TfR"), as the first Accepted Fcab Target and in May 2018, Denali exercised its right to nominate two additional Fcab targets and identified a second Accepted Fcab Target.

Under the Denali License and Collaboration Agreement, Denali was responsible for payment of certain research costs incurred by us in conducting activities under each agreed development plan, for up to 24 months. The last of the agreed development plans concluded in February 2021, with us having no ongoing obligation to conduct research activities under the Denali License and Collaboration Agreement.

Under the terms of the Denali agreements, we are prohibited from developing, commercializing and manufacturing any antibody or other molecule that incorporates any Fcab directed to an Accepted Fcab Target, or any such Fcab as a standalone product, and from authorizing any third party to take any such action.

2018 Agreement with Iontas Limited

In March 2018, we entered into an agreement (the "Iontas Agreement"), with Iontas Limited ("Iontas"), pursuant to which we acquired all Iontas' right, title and interest in and to certain anti-PD-L1 human antibodies. Additionally, Iontas granted us a worldwide, exclusive license under any know-how or related intellectual property rights to exploit any products containing such antibodies. In connection with the Iontas Agreement, an upfront payment of $0.3 million was made by us to Iontas.

Pursuant to the Iontas Agreement, we are obligated to pay an annual fee of £0.1 million ($0.1 million) and up to £0.4 million ($0.5 million) in the aggregate for certain specified preclinical milestones on a per product basis. We are obligated to pay Iontas up to £13.0 million ($17.7 million) in the aggregate upon the achievement of certain development and regulatory milestones and up to £12.8 million ($17.3 million) in the aggregate upon the achievement of certain commercial milestones, in each case on a per product basis.

Unless earlier terminated, the term of the Iontas Agreement will continue in perpetuity. We may terminate the Iontas Agreement upon specified prior written notice. Additionally, either party may terminate the Iontas Agreement in the event of an uncured material breach under the Iontas Agreement by the other party or for certain bankruptcy or insolvency events involving the other party.

2018 Amended and Restated PD-LI License Agreements with Kymab Limited

Out-License Agreement

In November 2018, we entered into a license agreement (the "Kymab Out-License Agreement"), with Kymab Limited ("Kymab"), which amended and restated an original agreement dated April 19, 2016, pursuant to which we granted Kymab an exclusive license to certain of our patents and a non-exclusive license to certain of our know-how to research, develop, manufacture, use and commercialize antibodies comprising a PD-L1 Fcab and an Inducible T-Cell Co-Stimulator Fab component, or licensed products, for all therapeutic, prophylactic and diagnostic uses, including the treatment of human and animal disease.

Under the Kymab In-License Agreement, we must use commercially reasonable efforts to develop and commercialize a licensed product. During the term of the Kymab In-License Agreement, we are subject to certain non-compete obligations, provided that such obligations shall cease upon the termination or expiration of the Kymab Out-License Agreement.

Pursuant to the Kymab Out-License Agreement, we are entitled to receive a percentage of sublicensing revenue received by Kymab ranging in the low to high single digits. In the event that Kymab is acquired by a third party prior to entering into a sublicense agreement with respect to a licensed product, or, in the case where the acquirer is the sublicensee, then, in lieu of our right to receive a percentage of sublicensing revenue, we are entitled to receive development and regulatory milestones of up to £4.75 million ($6.4 million) in the aggregate, commercial milestones of up to £7.5 million ($10.2 million) in the aggregate and a low-single digit royalty on net sales of licensed products. In the event that Kymab sells licensed products, we are eligible to receive a low-single digit royalty on these net sales on a licensed product-by-product basis. Our right to receive royalties under the Kymab Out-License Agreement expires, on a licensed product-by-licensed product and country-by-country basis, on the first to occur of: (i) the expiration, invalidation or abandonment date of the last valid licensed patent claim that relates to the manufacture, sale or use of such licensed product in such country, and (ii) the tenth anniversary of the first commercial sale of such licensed product anywhere in the world.

Unless earlier terminated, the term of the Kymab Out-License Agreement will continue in perpetuity. Kymab may terminate the Kymab Out-License Agreement for convenience at any time effective upon expiration of a certain specified notice period. We may terminate the Kymab Out-License Agreement in the event of an uncured material breach under the agreement by Kymab. We may terminate Kymab's rights under the Kymab Out-License Agreement if Kymab challenge any patent licensed to it under the Kymab Out-License Agreement. Kymab may terminate our rights under the Kymab Out-License Agreement if we challenge any patent controlled by Kymab.

In-License Agreement

In November 2018, we entered into a license agreement (the "Kymab In-License Agreement"), with Kymab, which amended and restated an original agreement dated April 19, 2016, pursuant to which we obtained from

Kymab an exclusive license to certain of Kymab's patents and a non-exclusive license to certain of Kymab's know-how to research, develop, manufacture, use and commercialize antibodies comprising a LAG-3 Fcab and a single specified anti-PD-L1 Fab component, or licensed products, for all therapeutic, prophylactic and diagnostic uses, including the treatment of human and animal disease.

Under the Kymab In-License Agreement, we must use commercially reasonable efforts to develop and commercialize a licensed product. During the term of the Kymab In-License Agreement, we are subject to certain non-compete obligations, provided that such obligations shall cease upon the termination or expiration of the Kymab Out-License Agreement.

Pursuant to the Kymab In-License Agreement, we are obligated to pay Kymab a percentage of sublicensing revenue ranging in the low to high single digits. In the event that we are acquired by a third party prior to entering into a sublicense agreement with respect to a licensed product, or, in the case where the acquirer is the sublicensee, then, in lieu of our obligation to pay Kymab a percentage of sublicensing revenue, we are obligated to pay Kymab development and regulatory milestones of up to £4.75 million ($6.4 million) in the aggregate, commercial milestones of up to £7.5 million ($10.2 million) in the aggregate and a low-single digit royalty on net sales of licensed products. In the event that we sell licensed products, we are obligated to pay Kymab a low-single digit royalty on these net sales. Our obligation to pay royalties under the Kymab In-License Agreement expires, on a licensed product-by-licensed product and country-by-country basis, on the first to occur of: (i) the expiration, invalidation or abandonment date of the last valid licensed patent claim that relates to the manufacture, sale or use of such licensed product in such country, and (ii) the tenth anniversary of the first commercial sale of such licensed product anywhere in the world.

Unless earlier terminated, the term of the Kymab In-License Agreement will continue in perpetuity. We may terminate the Kymab In-License Agreement for convenience at any time effective upon expiration of a certain specified notice period. Kymab may terminate the Kymab In-License Agreement in the event of an uncured material breach under the agreement by us. Kymab may terminate our rights under Kymab In-License Agreement if we challenge any patent licensed to it under the Kymab In-License Agreement. We may terminate Kymab's rights under the Kymab In-License Agreement if Kymab challenges any patent controlled by us.

2019 License and Collaboration Agreement with Ares Trading S.A., an affiliate of Merck KGaA, Darmstadt, Germany (as amended, July 2020)

On May 13, 2019, we entered into a license and collaboration agreement (the "Ares Agreement"), with Ares, pursuant to which we granted Ares the option to enter into a worldwide, exclusive license to certain of our patents and know-how to develop, manufacture and commercialize two separate mAb^2 antibody products that each contain a specific Fcab and a Fab target pair (each a licensed product), in the field of the treatment and prevention of diseases in humans.

Under the Ares Agreement, we received reimbursement of our internal and external development costs for each preclinical program. Under the Ares Agreement we conducted certain mutually agreed upon preclinical development activities and delivered data packages to Ares. Following receipt of each data package, Ares had the option to continue with the program and if Ares elected to continue with the program, Ares would be solely responsible for the continued development, manufacture and commercialization of the applicable licensed products. Ares exercised its option in relation to one of the preclinical programs (the "First Program") on May 13, 2019 and exercised its option in relation to the second preclinical program (the "Second Program") in July 2020.

In July 2020, the Ares Agreement was amended such that we granted Ares a time-limited option to enter into a worldwide, exclusive license to develop, manufacture and commercialize two additional mAb^2 products (the "Third Program" and the "Fourth Program") in the field of the treatment and prevention of diseases in humans. With respect to the Third Program and Fourth Program, we are not required to deliver data packages to

Ares, and upon exercise of each option Ares will be solely responsible for the continued development, manufacture and commercialization of the applicable licensed products.

During the term of the Ares Agreement, we are subject to certain non-compete obligations.

Pursuant to the Ares Agreement, Ares paid €10 million ($11.2 million) in connection with the exercise of the option for the First Program and €7.5 million ($8.5 million) in connection with the exercise of the option for the Second Program. Additionally, Ares is obligated to pay us up to €408.5 million ($501.7 million) in the aggregate for the programs upon the achievement of certain development and regulatory milestones and up to €252 ($309.5 million) in the aggregate upon the achievement of certain commercial milestones. We are eligible to receive a low single digit royalty on net sales of licensed products. The royalties payable to us under the Ares agreement may be reduced under certain circumstances. Our right to receive royalties under the Ares Agreement expires, on a licensed product-by-licensed product and country-by-country basis, on the latest of: (i) the expiration, invalidation or abandonment date of the last valid licensed patent claim that relates to such licensed product in such country, (ii) the expiration of regulatory exclusivity for such licensed product in such country and (iii) the twelfth anniversary of the first commercial sale of such licensed product in such country.

In connection with the Ares Agreement, we also granted Ares the right to negotiate a royalty agreement in the event of commercialization of FS118, and we reserved the right to receive a license to Ares' FS118 manufacturing technology and a transfer of certain materials, provided such technology is not subject to a legal restriction. If this royalty agreement is entered into, we may be obligated to pay Ares a low single digit royalty on net sales of FS118 products, subject to certain reductions.

Unless earlier terminated, the term of the Ares Agreement will expire on a program-by-program basis on the date on which Ares has no further milestone or royalty obligations with respect to such program. We may terminate the Ares Agreement if Ares or any sublicensee challenges any patent licensed to it under the Ares Agreement. Ares may terminate the Ares Agreement on a program-by-program basis for convenience at any time effective upon expiration of certain specified notice periods. Either us or Ares may terminate the Ares Agreement in the event of an uncured material breach under the agreement by the other party or for certain bankruptcy or insolvency events involving the other party; provided, however that, in the event of our uncured material breach, under certain circumstances Ares may elect not to terminate the Ares Agreement and instead, as its sole remedy, to reduce future milestone and royalty payments by an agreed upon amount.

Manufacturing

We do not currently own or operate manufacturing facilities for production of clinical or commercial quantities of any of our drug candidates or their components. We currently generate batches of our mAb^2 bispecific antibody candidates in our laboratories for initial preclinical studies using standardized procedures. We rely on and expect to continue to rely on third-party contract manufacturing organizations ("CMOs"), to manufacture clinical materials and any future commercial materials for our product candidates. We require our CMOs to produce bulk drug substance and finished drug product in accordance with current Good Manufacturing Practices and all other applicable laws and regulations. We maintain agreements with our CMOs that include confidentiality and intellectual property provisions to protect our proprietary rights related to our product candidates. We believe that both the standard IgG platform processes used for mAb^2 manufacturing and chemical synthesis used for SB 11285 manufacturing can be transferred to a number of other CMOs for the production of clinical and commercial supplies of our product candidates in the ordinary course of business.

Competition

The biotechnology and pharmaceutical industries, in developing novel and proprietary therapies for the treatment of cancer, are characterized by rapidly advancing technologies and innovation, intense competition and a strong emphasis on intellectual property. We believe that our differentiated technology, dominant intellectual

property position, significant development experience and scientific knowledge provide us with competitive advantages. However, we face potential competition from many different sources, including large biotechnology and pharmaceutical companies, academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for the research, development, manufacturing and commercialization of oncology therapies. We anticipate that we will face intense and increasing competition from the constantly evolving therapeutic landscape, as new drugs and therapies enter the market and advanced technologies become available. Any product candidates that we successfully develop and commercializes will compete with new oncology therapies that may become available in the future.

We compete in the segments of the biotechnology, pharmaceutical and other related markets that develop immuno-oncology therapies. There are many other companies that have commercialized and/or are developing immuno-oncology therapies for cancer including large biotechnology and pharmaceutical companies, such as AstraZeneca, BMS, EMD Serono, Genentech, a member of the Roche Group, Lilly, MSD, Novartis, Pfizer, and Sanofi. Several companies, not limited to those above, are attempting to combine immuno-oncology antibody therapies in order to modulate two cancer pathways simultaneously. Others have developed bispecific antibodies in order to leverage the effect of a combination of single-target traditional antibodies in a single molecule.

With respect to our mAb 2 bispecific antibody pipeline, we are aware of several competitors using other technology methods to create bispecific antibodies to treat a variety of cancer types, including, but not limited to Genmab A/S, Inhibrx, MacroGenics, Merus, Pieris Pharmaceuticals, Hoffman-LaRoche, Shattuck Labs, and Xencor, Inc.

With respect to our lead mAb 2 product candidate, FS118, we are aware of other competing molecules targeting LAG-3 and PD-1/PD-L1 receptors. Companies pursuing a bispecific molecule directed against LAG-3 and PD-1/PD-L1 in different phases of clinical development include but are not limited to Epimab, MacroGenics and Hoffmann-La Roche. We are also aware of other companies pursuing a combination of two traditional antibodies in different phases of clinical development, with the targeting PD-1/PD-L1, and one targeting LAG-3, which include but are not limited to: BMS, C.H. Boehringer Sohn AG & Co. KG and MSD.

With respect to our second mAb 2 product candidate, FS120, we are aware of other companies pursuing bispecific antibodies targeting OX40 and CD137, which include but are not limited to Aptevo Therapeutics. We are also aware that Pfizer s has ongoing clinical studies evaluating a combination of CD137 plus OX40 traditional antibodies.

With respect to our third mAb 2 product candidate, FS222, we are aware of other companies pursuing bispecific antibodies targeting PD-L1 and CD137 in clinical development, which include but are not limited to: Genmab/BioNTech SE, Inhibrx/Elpiscience, Merus/Incyte and Numab Therapeutics AG/CStone Pharmaceuticals. We are also aware of other companies that are pursuing a combination of two traditional antibodies in clinical development, with the targeting PD-1/PD-L1, and one targeting CD137, which include but are not limited to: Adagene, BMS, Lyvgen Biopharma (Suzhou)/MSD, Pfizer, and Hoffman LaRoche.

With respect to our fourth product candidate, SB 11285, we are aware of other companies pursuing a second generation, intravenously administered STING agonist, in clinical development which include but are not limited to: GSK, Millennium Therapeutics/ Takeda, and Silicon Therapeutics.

Many of the companies against which we are competing or against which we may compete in the future, either alone or with their strategic collaborators, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved drugs than we do. Mergers and acquisitions in the biotechnology, pharmaceutical and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors,

particularly through unforeseen technological innovations, or collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and enrolling patients for our clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA, EMA or other foreign regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Intellectual Property

We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to the development of our business, including seeking, maintaining and defending patent rights, whether developed internally or licensed from third parties. We also rely on trade secrets relating to our proprietary modular antibody technology platform and on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain our proprietary position in the immuno-oncology field and other fields that are or may be important for the development of our business. We additionally expect to rely on regulatory protection afforded through orphan drug designations, data exclusivity, market exclusivity and patent term extensions where available.

Our commercial success may depend in part on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; defend and enforce our patents; preserve the confidentiality of our trade secrets; and operate without infringing the valid enforceable patents and proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell or importing our products may depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our commercial products and methods of manufacturing the same.

We have developed or in-licensed numerous patents and patent applications and possesses substantial know-how and trade secrets relating to the development and commercialization of our mAb^2 product candidates and the underlying modular antibody technology platform and have also acquired a patent family relating to our STING agonist product candidate, SB 11285. To date, our patent estate includes over 230 granted patents and over 180 pending patent applications generally directed to, for example, compositions and methods related to our Fcabs, our modular antibody technology platform, our lead mAb^2 product development candidates, our STING agonist SB 11285 and other STING agonist compounds, and other products, proprietary technologies and processes.

The patent portfolios for the fields containing our most advanced mAb ^{2} product candidates as of the date of this Annual Report are summarized below.

FS118 (LAG-3/PD-L1 mAb^2)

Our patent portfolio related to FS118 includes 12 owned or licensed patent families, which relate generally to the FS118 mAb ^{2} bispecific antibody composition of matter, the LAG-3 Fcab and PD-L1 mAb antibody included in FS118, methods of producing these molecules and use of the FS118 mAb^2 bispecific antibody in the treatment of cancer.

Specifically, we solely own two FS118-focused patent families which relate to the FS118 mAb ^{2} bispecific antibody composition of matter and the LAG-3 Fcab included in FS118, respectively, as well as methods of

producing these molecules and use of the FS118 mAb 2 bispecific antibody or LAG-3 Fcab in the treatment of cancer. Patent applications are pending in each of these families in major territories worldwide, including Australia, Canada, China, Europe, Japan and the United States. Any patents that may issue from these pending applications are expected to expire in 2037, absent any patent term adjustments or extensions and subject to the potential effect of any terminal disclaimers.

We also solely own a third FS118-focused patent family directed to FS118 dosing schedules. This patent family consists of a pending international application filed under the Patent Cooperation Treaty ("PCT") in 2020. Any patents that may derive from this international application will be expected to expire in 2040, absent any patent term adjustments or extensions and subject to the potential effect of any terminal disclaimers.

Further, we solely own patent families which relate to our modular antibody technology platform, including aspects of the underlying Fcab and mAb2 bispecific antibody technologies utilized in FS118. Issued patents in these families are expected to expire between 2026 and 2027, absent any patent term adjustments or extensions and subject to the potential effect of any terminal disclaimers. Our modular antibody technology platform portfolio is discussed in more detail below.

Finally, we have an exclusive license to research, develop, manufacture, use and commercialize FS118 from Kymab under a number of patents related to the PD-L1 mAb utilized in FS118. Patents are expected to expire up to 2036, absent any patent term adjustments or extensions and subject to the potential effect of any terminal disclaimers.

FS120 (OX40/CD137 mAb²)

Our patent portfolio related to FS120 includes six patent families, solely owned by us, which relate generally to the FS120 mAb 2 bispecific antibody composition of matter, the OX40 Fcab and CD137 antibody included in FS120, methods of producing the mAb 2 bispecific antibody and use of the FS120 mAb2 bispecific antibody in the treatment of cancer.

Specifically, we solely own three patent families which relate to the composition of matter of the OX40 Fcab included in FS120, the CD137 antibody included in FS120, and the FS120 mAb2 bispecific antibody, respectively, as well as methods of producing such compositions and use of the compositions in the treatment of cancer. Patent applications are pending in each of these families in major territories worldwide, including Australia, Canada, Europe, Japan and the United States. Any patents that may issue from these patent applications will be expected to expire in 2039, absent any patent term adjustments or extensions and subject to the potential effect of any terminal disclaimers.

Further, the F-star patent families relating to our modular antibody technology platform discussed in more detail below include aspects of the underlying Fcab and mAb2 technologies utilized in FS120.

FS222 (CD137/PD-L1 mAb²)

Our patent portfolio related to FS222 includes seven patent families, solely owned by us, which relate generally to the FS222 mAb 2 bispecific antibody composition of matter, the CD137 Fcab and PD-L1 antibody included in FS222, methods of making the mAb 2 bispecific antibody and use of the FS222 mAb2 bispecific antibody in treatment of cancer.

Specifically, we solely own three patent families which relate to the composition of matter of the CD137 Fcab included in FS222, the PD-L1 antibody included in FS222 (acquired under agreement from Iontas), and the FS222 mAb 2 bispecific antibody, respectively, as well as methods of producing such compositions and use of the compositions in the treatment of a disease, such as cancer. Patent applications are pending in each of these families in major territories worldwide, including Australia, Canada, Europe, Japan and the United States. Any patents that may issue from these pending applications will be expected to expire in 2039, absent any patent term adjustments or extensions and subject to the potential effect of any terminal disclaimers.

We also solely own one patent family related to FS222 which relates to mAb ^{2} bispecific antibodies that bind both a tumor antigen and a tumor necrosis factor receptor superfamily (TNFRSF) receptor on the surface of an immune cell and methods of producing and use of the same in the treatment of cancer. This patent family contains pending patent application in Australia, Canada, China, Europe, Japan, South Korea and the United States. Any patents that may issue from these pending applications will be expected to expire in 2038, absent any patent term adjustments or extensions and subject to the potential effect of any terminal disclaimers.

Additionally, our patent families relating to our modular antibody technology platform discussed below include aspects of the underlying Fcab and mAb^2 technologies utilized in FS222.

Platform Technology

Our patent portfolio also includes numerous patents and patent applications generally relating to our modular antibody technology platform and other products and programs not currently under development by us.

Specifically, we own patent families relating to our modular antibody technology platform, including two patent families that are generically related to the technology, one family that relates to both the mAb^2 technology and the Fcab technology, and one family that relates to improved methods for selecting functional Fcabs. Included in these four patent families are six issued U.S. patents, four pending U.S. patent applications, more than 200 issued ex-U.S. patents, and nine pending ex-U.S. patent applications. Patents in these families are expected to expire between 2026 and 2028, absent any patent term adjustments or extensions and subject to the potential effect of any terminal disclaimers.

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued for regularly filed applications in the United States are granted a term of 20 years from the earliest effective non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the U.S. Patent and Trademark Office delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. Where a U.S. patent is subject to a terminal disclaimer, the term of the patent may alternatively be shorter than 20 years.

SB 11285 (STING agonist compound)

Our patent portfolio related to SB 11285 includes a patent family, solely owned by us, which includes claims directed generally to the composition of matter of a series of STING agonist compounds encompassing SB 11285, specifically to the composition of matter of SB 11285, as well as to methods of using such compounds to treat cancer. Patent applications are pending in this family in major territories worldwide, including Australia, Canada, China, Europe, Japan, South Korea and the United States. Any patents that may issue from these pending applications will be expected to expire in 2037, absent any patent term adjustments or extensions and subject to the potential effect of any terminal disclaimers.

Government Regulation and Product Approval

In the United States, the FDA regulates therapeutics like our mAb ^{2} product candidates as biological products, or biologics, and therapeutics like SB 11285 as drugs under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and related regulations. Biologics and drugs are also subject to other federal, state, local and foreign statutes and regulations. Failure to comply with the applicable U.S. regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant to significant fines and penalties, including administrative or judicial actions. These actions could include, for example, the suspension or termination of clinical trials by the FDA or an Institutional Review Board ("IRB"), the FDA's refusal to approve pending applications or supplements, revocation of a biologics license, warning

letters, product recalls, product seizures, total or partial suspension of production or distribution, import detention, injunctions, civil penalties or criminal prosecution. Any such penalty or enforcement action could have a material adverse effect on us.

The U.S. Food and Drug Administration ("FDA") and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of biologics and drugs. These agencies and other federal, state, local and foreign entities regulate, among other things, research and development activities and the testing, manufacture, quality control, effectiveness, safety, purity, potency, labeling, packaging, storage, distribution, record keeping and reporting, approval, import and export, advertising and promotion and post-market surveillance of biologics and drugs.

The FDA's and comparable regulatory agencies' policies may change, and additional government regulations may be enacted that could prevent or delay regulatory approval of any future product candidates or approval of product or manufacturing changes, new disease indications, or label changes. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

Product Development

In the United States, the FDA regulates human drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and in the case of biological products, or biologics, also under the Public Health Service Act, or the PHSA, and their implementing regulations. SB 11285 are drugs. Biologics and drugs are also subject to other federal, state, local and foreign statutes and regulations. Failure to comply with the applicable U.S. regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant to significant fines and penalties, including administrative or judicial actions. These actions could include, for example, the suspension or termination of clinical trials by the FDA or an Institutional Review Board ("IRB"), the FDA's refusal to approve pending marketing applications or supplemental applications, revocation of a biologics license or new drug approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, import detention, injunctions, civil penalties or criminal prosecution. Any such penalty or enforcement action could have a material adverse effect on us.

The process required by the FDA before a biologic or drug may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices, commonly "GLPs", and applicable requirements for the human use of laboratory animals or other applicable regulations;
- submission of an Investigational New Drug ("IND") application, which must become effective before clinical trials may begin;
- approval of the protocol and related documentation by an independent IRB or ethics committee at each clinical trial site before each study may be initiated;
- performance of adequate and well-controlled human clinical trials according to the FDA's IND regulations, current good clinical practices, or "GCPs", and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the investigational product for each proposed indication;;
- submission to the FDA of a Biologics License Application ("BLA") or a New Drug Application ("NDA"), for marketing approval, including payment of application user fees;
- satisfactory completion of FDA pre-approval inspections of manufacturing facilities where the biologic or drug is produced to assess compliance with current Good Manufacturing Practice ("GMP") requirements to assure that the facilities, methods and controls are adequate to preserve the biologic's or drug's identity, strength, quality and purity;

- potential FDA audits of the nonclinical study and clinical trial sites that generated the data in support of the BLA or NDA; and
- FDA review and approval of the BLA or NDA, including satisfactory completion of an FDA advisory committee review of the product candidate, where appropriate or if applicable, which must occur before the biologic or drug can be marketed or sold in the United States.

The testing and approval process requires substantial time and financial resources, and we cannot be certain that any new approvals for our product candidates will be granted on a timely basis, if at all.

Preclinical Studies

Before testing any compound or biological product candidate in human subjects, a company must develop extensive preclinical data. Preclinical tests, also referred to as nonclinical studies, generally include laboratory evaluations of product compound or biological characteristics, chemistry and formulation as well as toxicological and pharmacological studies in several animal species to assess the potential quality, safety and activity of the product. Nonclinical studies must be performed in compliance with the FDA's GLP regulations and, as applicable, the U.S. Department of Agriculture's Animal Welfare Act and related regulations.

Prior to commencing the first clinical trial in humans, an IND application must be submitted to the FDA. A company must submit preclinical testing results, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. An IND is a request for authorization from the FDA to ship an unapproved, investigational product in interstate commerce and to administer it to humans, and it must become effective before clinical trials may begin. The IND application automatically becomes effective 30 days after receipt by the FDA unless the FDA within the 30-day time period raises concerns or questions about the conduct of the clinical trial and places the trial on clinical hold. In such case, the IND application sponsor must resolve any outstanding concerns with the FDA before the clinical trial may begin. The FDA also may impose clinical holds on a product candidate at any time before or during clinical trials due to, among other considerations, unreasonable or significant safety concerns, inability to assess safety concerns, lack of qualified investigators, a misleading or materially incomplete investigator brochure, study design deficiencies, interference with the conduct or completion of a study designed to be adequate and well-controlled for the same or another investigational product, insufficient quantities of investigational product, lack of effectiveness or non-compliance. If the FDA imposes a clinical hold, studies may not recommence without FDA authorization and then only under terms authorized by the FDA.

Human Clinical Trials

Clinical trials involve the administration of a biological or drug product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the study sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objective of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND.

Informed consent must also be obtained from each study subject. Further, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and related documentation, including the form and content of the informed consent that must be signed by each study subject or his or her legal representative, before the trial commences at that site. The IRB for each site also monitors the clinical trial until completed. Regulatory authorities, an IRB, a data safety monitoring board or the study sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the participants are being exposed to an unacceptable safety risk.

A clinical trial sponsor is required to submit to the National Institutes of Health ("NIH") for public posting on NIH's clinical trial website details about certain active clinical trials and clinical trial results. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Although sponsors are obligated to disclose the results of their clinical trials after completion, disclosure of the results can be delayed in some cases for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. The NIH's Final Rule on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and both NIH and FDA recently signaled the government's willingness to begin enforcing those requirements against non-compliant clinical trial sponsors.

Human clinical trials are typically conducted in the following phases, which may overlap:

- Phase 1 — the product candidate is initially given to healthy human subjects or patients and tested for safety, dosage tolerance, reactivity, absorption, metabolism, distribution and excretion. These trials may also provide early evidence of effectiveness. During Phase 1 clinical trials, sufficient information about the investigational product's activity may be obtained to permit the design of well-controlled and scientifically valid Phase 2 clinical trials.
- Phase 2 — clinical trials are conducted in a limited number of patients in the target population to identify possible adverse effects and safety risks, to evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3 — when Phase 2 evaluations demonstrate that a dosage range of the product appears effective and has an acceptable safety profile and provide sufficient information for the design of Phase 3 clinical trials, Phase 3 clinical trials are undertaken to provide statistically significant evidence of clinical efficacy and to further test for safety in an expanded patient population at multiple clinical trial sites. Phase 3 clinical trials are performed after preliminary evidence suggesting effectiveness of the biologic has been obtained, and they are intended to further evaluate dosage, effectiveness and safety, to establish the overall benefit-risk relationship of the investigational biologic, and to provide an adequate basis for product approval by the FDA.

All of these trials must be conducted in accordance with GCP requirements in order for the data to be considered reliable for regulatory purposes. Further, during all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or *in vitro* testing that suggests a significant risk for human subjects or any clinically important increase in the rate of a serious adverse reactions over that listed in the protocol or investigator brochure. The sponsor must submit such an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 clinical trials may be made a condition to be satisfied for continuing product approval. The results of Phase 4 clinical trials can confirm the effectiveness of a product candidate and can provide important safety information. Conversely, the results of Phase 4 clinical trials can raise new safety or effectiveness issues that were not apparent during the original review of the product, which may result in product restrictions or even withdrawal of product approval. If any of our products are subject to post-marketing requirements and commitments, there may be resource and financial implications for our business.

Marketing Application Submission and FDA Review

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of either a BLA or an NDA requesting approval to market the biologic or drug product for one or more indications. A BLA in particular must contain proof of the biological product candidate's safety, purity, potency and efficacy for its proposed indication or indications. In order to obtain approval to market a therapeutic product in the United States, the marketing application must provide data establishing to the FDA's satisfaction, among other things, the safety and effectiveness of the investigational product for the proposed indication. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product. In addition, the application may include supplemental data from a number of alternative sources, including studies initiated by investigators. Under federal law, the fee for the submission of an NDA or BLA is substantial (for example, for FY2021 this application fee exceeds $2.8 million), and the sponsor of an approved NDA or BLA is also subject to an annual program fee, currently more than $336,000 per program. These fees are typically adjusted annually, but exemptions and waivers may be available under certain circumstances.

The FDA will initially review a BLA or NDA for completeness before it accepts the application for filing. Under the FDA's procedures, the agency has 60 days from its receipt of a BLA/NDA, also called the filing period, to determine whether the application will be accepted for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. After the BLA or NDA submission is accepted for filing, the FDA reviews the application to determine, among other things, whether the proposed product is safe and effective for its intended use, whether it has an acceptable purity profile (for biologics), and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity (as applicable depending on if the product is a drug or a biologic). The FDA may request additional information rather than accept a BLA or NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review process of BLAs and NDAs. Under that agreement, 90% of New Molecular Entity ("NME") NDAs and original BLAs, are meant to be reviewed within ten months from the date on which FDA accepts the NDA or BLA for filing, and 90% of applications for NMEs or new biological products that have been designated for "Priority Review" are meant to be reviewed within six months of the filing date. For applications seeking approval of drugs that are not NMEs, the ten-month and six-month review periods run from the date that FDA receives the application. The FDA may extend the review process and the Prescription Drug User Fee Act goal date for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission. Moreover, despite these review goals, it is not uncommon for FDA review of a BLA or NDA to extend beyond the goal date.

Before approving a BLA or NDA, the FDA typically will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. These pre-approval inspections may cover all facilities associated with the BLA or NDA submission, including drug component manufacturing (e.g., active pharmaceutical ingredient manufacturers included within an NDA), finished product manufacturing, and control testing laboratories. Additionally, before approving a BLA or NDA, the FDA may inspect one or more clinical sites to assure compliance with GCP. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it typically will outline the deficiencies and often will request additional testing or information. This may significantly delay further review of the application. If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCP, the FDA may, for example, determine the data generated by the clinical site should be excluded from the primary efficacy analyses provided in the BLA or NDA. Additionally, notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, and it is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making its approval decisions.

During the review and approval process, the FDA likely will re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. In addition, as a condition of approval, the FDA may require an applicant to develop a risk evaluation and mitigation strategy, or REMS, if it determines that a REMS is necessary to assure the safe use of the drug or biological product. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. When determining on a case-by-case basis whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events and whether the product is an NME. REMS can include medication guides, physician communication plans for healthcare professionals and elements to assure safe use ("ETASU"). ETASU may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, restricted distribution requirements, special clinical monitoring and/or the use of patient registries. The FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS can materially affect the potential market and profitability of an approved drug or biological product.

Based on the FDA's evaluation of a BLA or an NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA or NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. In addition, when a complete response letter is issued, the sponsor may elect to either resubmit the BLA or NDA or withdraw the application. Resubmitting a BLA or NDA in response to a complete response letter can add additional time to the approval process for a product.

Under the Pediatric Research Equity Act, or "PREA", as amended, an initial BLA/NDA or certain supplements to a BLA/NDA for a novel product must contain data to assess the safety and effectiveness of the product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of pediatric data until after approval of the product for use in adults or full or partial waivers from the pediatric data requirement. Unless otherwise required by regulation, PREA does not typically apply to any therapeutic product for an indication for which orphan designation has been granted. The Food and Drug Administration Safety and Innovation Act, or "FDASIA", enacted in 2012, made permanent the PREA requirement that a sponsor who is planning to submit a marketing application for a product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan ("PSP"), within sixty days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 clinical trial. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including trial objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral

of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from pre-clinical studies, early phase clinical trials or other clinical development programs.

The testing and approval process for a novel biologic or drug requires substantial time, effort and financial resources and this process may take several years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the biologic's or drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product, including imposition of restrictions and conditions on product distribution, prescribing, or dispensing in the form of a REMS, requirements to conduct additional studies or trials, or even complete withdrawal of the product from the market. In addition, F-star cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

U.S. Post-Approval Requirements

Any therapeutic products manufactured or distributed by is or on our behalf pursuant to FDA approvals will be subject to continuing regulation by the FDA, including requirements for record-keeping, reporting of adverse experiences with the biologic or drug, and submitting product deviation reports to notify the FDA of unanticipated changes in distributed products. In addition, all manufacturers are required to register their facilities with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP standards and other laws. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. This will require us and any third-party manufacturers to implement certain quality processes, manufacturing controls and documentation requirements in order to ensure that every product is safe for use, has the identity and strength it claims to have (for both a drug and a biologic) and meets the quality, purity and potency characteristics that it purports to have (for a biologic). There are continuing, annual program fee requirements for any marketed products, as well as new application fees for supplemental applications with clinical data.

We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP and other FDA regulatory requirements. If our present or future suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, refuse to approve any BLA, NDA or other application, force us to recall a product from distribution, shut down manufacturing operations or withdraw approval of the BLA or NDA for that biologic or drug. Noncompliance with cGMP or other requirements can also result in issuance of warning letters, civil and criminal penalties, seizures, and injunctive action. The distribution of prescription products is subject to additional state requirements and regulations, including record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of prescription drug and biological products.

The FDA and other federal and state agencies closely regulate the labeling, marketing and promotion of biologics and drugs. While doctors may prescribe any product approved by the FDA for unapproved uses or patient populations (known as “off-label” uses), manufacturers may not market or promote such uses. In addition, biologic and drug promotional materials must be submitted to the FDA in conjunction with their first publication or first dissemination. (or, in the case of product candidates approved under the accelerated approval regulations, prior to dissemination). Further, if there are any modifications to the biologic or drug, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or NDA or a BLA or NDA supplement, which may require the applicant to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, injunctions, potential civil and criminal penalties, criminal prosecution or agreements with governmental agencies that materially restrict the manner in which a product approved by FDA may be promoted or distributed, among other potential consequences.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or “PDMA”, which regulates the distribution of drugs and biological product samples at the federal level and sets minimum standards for the registration and regulation of prescription drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. Most recently, the Drug Supply Chain Security Act, or “DSCSA”, was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States, including most biological products. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10 year period that is expected to culminate in November 2023. From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

FDA’s Regulation of Companion Diagnostics

We believe that the success of certain of our product candidates, if approved, may depend, in part, on the development and commercialization of a companion diagnostic. Companion diagnostics identify patients who are most likely to benefit from a particular therapeutic product; identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness. Companion diagnostics are regulated as in vitro diagnostic medical devices by the FDA. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import and post-market surveillance. Unless an exemption applies, diagnostic tests generally require marketing clearance or approval from the FDA prior to commercialization. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval (“PMA”).

To obtain 510(k) clearance for a medical device, or for certain modifications to devices that have received 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or to a pre-amendment device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for the submission of a PMA. The device upon which the premarket notification is based is referred to as the Predicate Device. In making a determination that the proposed device is substantially equivalent to a predicate device, the FDA compares the proposed device to the predicate device or predicate devices and assesses whether the proposed device is comparable to the Predicate Device or Predicate Devices with respect to intended use, technology,

design and other features which could affect safety and effectiveness. If the FDA determines that the proposed device is substantially equivalent to the predicate device or predicate devices, the proposed device may be cleared for marketing. The 510(k) premarket notification pathway generally takes from three to 12 months from the date the application is completed but can take significantly longer.

In contrast, PMA applications must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For diagnostic tests, a PMA application typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures analogous to the cGMP regulations for drugs and biologics. The FDA's review of an initial PMA application is expected to take between six to ten months, although the process typically takes longer, and may require several years to complete. If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny the approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. Once granted, PMA approval may be withdrawn by the FDA if compliance with post-approval requirements, conditions of approval or other regulatory standards is not maintained, or problems are identified following initial marketing.

In 2014, the FDA issued a final guidance document addressing the development and approval process for "In Vitro Companion Diagnostic Devices." According to the agency, for novel therapeutic products that depend on the use of a diagnostic test and where the diagnostic device could be essential for the safe and effective use of the corresponding therapeutic product, the marketing application for the companion diagnostic device should be developed and approved or cleared contemporaneously with the therapeutic, although the FDA recognizes that there may be cases when contemporaneous development may not be possible. However, in cases where a drug cannot be used safely or effectively without the companion diagnostic, the FDA's guidance indicates that the agency will generally not approve the drug without the approval or clearance of the diagnostic device. The FDA also issued a draft guidance in July 2016 setting forth the principles for co-development of an *in vitro* companion diagnostic device with a therapeutic product. The draft guidance describes principles to guide the development and contemporaneous marketing authorization for the therapeutic product and its corresponding *in vitro* companion diagnostic. Subsequently, in December 2018, the FDA published a draft guidance entitled "Developing and Labeling In Vitro Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products" that is intended to facilitate class labeling on diagnostic tests for oncology therapeutic products, where scientifically appropriate. The draft guidance notes that in some cases, if evidence is sufficient to conclude that the companion diagnostic is appropriate for use with a specific group or class of therapeutic products, the companion diagnostic's intended use should name the specific group or class of therapeutic products, rather than specific products.

Once cleared or approved, a companion diagnostic device must adhere to post-marketing requirements for medical device products including the requirements of FDA's Quality System Regulation, adverse event reporting, recalls and corrections along with product marketing requirements and limitations. Like drug and biologic makers, companion diagnostic makers are subject to unannounced FDA inspections at any time, during which the FDA will conduct an audit of the product(s) and the company's facilities for compliance with its authorities.

U.S. Orphan Drug and European Orphan Medicinal Product Designation and Exclusivity

The U.S. Orphan Drug Act provides incentives for the development of products intended to treat rare diseases or conditions, which are generally diseases or conditions that affect fewer than 200,000 individuals in

the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making a drug or biologic available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested and granted by the FDA before submitting a BLA or NDA. The benefits of orphan drug designation include research and development tax credits and exemption from FDA prescription drug user fees. Orphan designation, however, does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. After the FDA grants orphan designation, the identity of the applicant, as well as the name of the therapeutic agent and its designated orphan use, are disclosed publicly by the FDA.

Under PREA, submission of a pediatric assessment is not typically required for pediatric investigation of a product that has been granted orphan drug designation. However, under the FDA Reauthorization Act of 2017, or "FDASIA," the scope of the PREA was extended to require pediatric studies for products intended for the treatment of an adult cancer that are directed at a molecular target that are determined to be substantially relevant to the growth or progression of a pediatric cancer. In addition, the FDA finalized guidance in 2018 indicating that it does not expect to grant any additional orphan drug designation to products for pediatric subpopulations of common diseases. Nevertheless, FDA intends to still grant orphan drug designation to a drug or biologic that otherwise meets all other criteria for designation when it prevents, diagnoses or treats either (i) a rare disease that includes a rare pediatric subpopulation, (ii) a pediatric subpopulation that constitutes a valid orphan subset, or (iii) a rare disease that is in fact a different disease in the pediatric population as compared to the adult population. Generally, if a product that receives orphan designation receives the first FDA approval for the orphan indication, the product is entitled to orphan drug exclusivity, which means that for seven years, the FDA is prohibited from approving any other applications to market the same drug or biological product for the same indication, except in limited circumstances described further below. Orphan exclusivity does not block the approval of a different drug or biologic for the same rare disease or condition, nor does it block the approval of the same drug or biologic for different conditions. As a result, even if one of our product candidates receive orphan exclusivity, the FDA can still approve different drugs or biologics for use in treating the same indication or disease, which could create a more competitive market for us. Additionally, if a drug or biologic designated as an orphan product receives marketing approval for an indication broader than what was designated, it may not be entitled to orphan drug exclusivity.

Orphan exclusivity will not bar approval of another product with the same drug or biologic for the same condition under certain circumstances, including if a subsequent product with the same drug or biologic for the same condition is shown to be clinically superior to the approved product on the basis of greater efficacy or safety or a major contribution to patient care, or if the company with orphan drug exclusivity cannot assure the availability of sufficient quantities of the drug or biologic to meet the needs of persons with the disease or condition for which the drug or biologic was designated.

Similarly, the European Commission grants orphan medicinal product designation to products intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating, affecting not more than five in 10,000 people in the European Union. In addition, orphan drug designation can be granted if the drug is intended for a life-threatening or chronically debilitating condition in the European Union and without incentives it is unlikely that returns from sales of the drug in the European Union would be sufficient to justify the investment required to develop the drug. In order to receive orphan designation, there must also be no satisfactory method of diagnosis, prevention or treatment of the condition, or if such a method exists, the medicine in question must be of significant benefit to those affected by the condition. In addition, sponsors are required to submit to the EMA's Pediatric Committee and comply with a pediatric investigation plan or "PIP", in order to initiate pivotal clinical investigation and seek marketing authorization in the European Union, unless the particular product is eligible for a deferral or waiver of the requirement to submit a PIP. The requirement to submit a PIP is waived for specific medicines or classes of medicines that are likely to be ineffective or unsafe in part or all of the pediatric population, are intended for conditions that occur only in adults or do not represent a significant therapeutic benefit over existing treatments for pediatric patients.

Designated orphan medicinal products are entitled to a range of incentives during the development and regulatory review process, including scientific assistance for study protocols, a partial or total reduction in fees and eligibility for conditional marketing authorization. Once authorized, orphan medicinal products are entitled to ten years of market exclusivity in all EU member states. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the ten-year period with the consent of the marketing authorization holder for the original orphan medicinal product or if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities of such product. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if the similar product is established to be safer, more effective or otherwise clinically superior to the original orphan medicinal product. An EU member state can request that the period of market exclusivity be reduced to six years if it can be demonstrated at the end of the fifth year of market exclusivity that the criteria for orphan designation no longer apply, such as where the medicine is sufficiently profitable. The period of market exclusivity may be extended for an additional two years for medicines that have also complied with an agreed PIP.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent marketing exclusivity available in the United States and, if granted, it provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity for the approved drug or biological product. Under the Best Pharmaceuticals for Children Act ("BPCA"), certain therapeutic candidates may obtain an additional six months of exclusivity if the sponsor submits information requested in writing by the FDA, referred to as a Written Request, relating to the use of the active moiety of the product or therapeutic candidate in children. The data do not need to show the product to be effective in the pediatric population studied; rather, the additional protection is granted if the pediatric clinical study is deemed to have fairly responded to the FDA's Written Request. As part of the FDASIA in 2012, the United States Congress permanently reauthorized the BPCA in addition to the PREA.

Although the FDA may issue a Written Request for studies on either approved or unapproved indications, it may only do so where it determines that information relating to that use of a product or therapeutic candidate in a pediatric population, or part of the pediatric population, may produce health benefits in that population. The issuance of a Written Request does not require the sponsor to undertake the described studies. Moreover, the additional six-month period exclusivity may be granted if the BLA or NDA sponsor submits pediatric data that fairly respond to the written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

U.S. Reference Product Exclusivity for Biological Products

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), enacted as part of the Patient Protection and Affordable Care Act in March 2010, created a unique licensure framework for biosimilars in the United States, which could ultimately subject our biological product candidates, if approved for marketing, to direct competition from potential future biosimilars. A biosimilar product is defined as one that is highly similar to a reference biological product notwithstanding minor differences in clinically inactive components and for which there are no clinically meaningful differences between the follow-on biological product and the reference product in terms of the safety, purity and potency of the product. To date, the FDA has approved a number of biosimilars, and numerous biosimilars have been approved in Europe. The FDA has also issued several guidance documents outlining its approach to reviewing and approving biosimilars and interchangeable biosimilars.

Under the BPCIA, a manufacturer may submit an abbreviated application for licensure of a biologic that is biosimilar to or interchangeable with an FDA-licensed reference biological product. This abbreviated approval pathway is intended to permit a biosimilar to come to market more quickly and less expensively than if a "full" BLA were submitted, by relying to some extent on the FDA's previous review and approval of the reference

biologic to which the proposed product is similar. Additionally, under the BPCIA, a biosimilar may be licensed as an interchangeable product upon a demonstration that the proposed product can be expected to produce the same clinical results as the reference product in any given patient, and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch. Upon licensure by the FDA, an interchangeable biosimilar may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product, although to date no such products have been approved for marketing in the United States.

Under the abbreviated approval pathway, the biosimilar applicant must demonstrate that the product is biosimilar based on data from (1) analytical studies showing that the biosimilar product is highly similar to the reference product; (2) animal studies (including toxicity); and (3) one or more clinical studies to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved. In addition, the applicant must show that the biosimilar and reference products have the same mechanism of action for the conditions of use on the label, route of administration, dosage and strength, and the production facility must meet standards designed to assure product safety, purity and potency.

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the first approved interchangeable biologic product will be granted an exclusivity period of up to one year after it is first commercially marketed. If pediatric studies are performed and accepted by the FDA as responsive to a Written Request, as described above in the section called “Pediatric Exclusivity,” the 12-year exclusivity period will be extended for an additional six months.

In addition, the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. “First licensure” typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a supplement for the reference product for a subsequent application filed by the same sponsor or manufacturer of the reference product (or licensor, predecessor in interest or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength or for a modification to the structure of the biological product that does not result in a change in safety, purity or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the “first licensure” of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

The BPCIA is complex and only beginning to be interpreted and implemented by the FDA. As part of the Affordable Care Act, moreover, the future of the BPCIA is subject to uncertainty following a December 2019 Fifth Circuit Court of Appeals ruling that upheld a lower court’s finding that the individual mandate in the Affordable Care Act is unconstitutional. The Fifth Circuit also reversed and remanded the case to the district court to determine if other reforms enacted as part of the Affordable Care Act but not specifically related to the individual mandate or health insurance, including the BPCIA, could be severed from the rest of the Affordable Care Act so as not to be declared invalid. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case and has allocated one hour for oral arguments, which are expected to occur in the fall, with a decision likely to follow in 2021. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation and meaning of the BPCIA is subject to significant uncertainty.

New Drug Exclusivity and Marketing Applications for Follow-on Drugs

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress enacted Section 505(b)(2) of the FDCA and also established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs that are shown to contain the same active ingredients as, and to be bioequivalent to, drugs previously approved by the FDA pursuant to NDAs. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application ("ANDA"), to the agency. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, bioequivalence, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are "abbreviated" because they cannot include preclinical and clinical data to demonstrate safety and effectiveness. Instead, in support of such applications, a generic manufacturer must rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference-listed drug ("RLD").

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, the strength of the drug and the conditions of use of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug".

Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

In contrast, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. A Section 505(b)(2) applicant may eliminate the need to conduct certain preclinical or clinical studies, if it can establish that reliance on studies conducted for a previously approved product is scientifically appropriate. Unlike the ANDA pathway used by developers of bioequivalent versions of innovator drugs, which does not allow applicants to submit new clinical data other than bioavailability or bioequivalence data, the 505(b)(2) regulatory pathway does not preclude the possibility that a follow-on applicant would need to conduct additional clinical trials or nonclinical studies; for example, it may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness.

As part of the NDA review and approval process, applicants are required to list with the FDA each patent that has claims that cover the applicant's product or method of therapeutic use. Upon approval of a new drug, each of the patents listed in the application for the drug is then published in the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential follow-on competitors in support of approval of an ANDA or 505(b)(2) NDA.

When an ANDA applicant submits its application to the FDA, it is required to certify to the FDA concerning any patents listed for the reference product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. Moreover, to the extent that the Section 505(b)(2)

NDA applicant is relying on studies conducted for an already approved product, the applicant also is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

If the follow-on applicant does not challenge the innovator's listed patents, FDA will not approve the ANDA or 505(b)(2) application until all the listed patents claiming the referenced product have expired. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the follow-on applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA/505(b)(2) applicant.

An ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired. In particular, the Hatch-Waxman Amendments provided a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity ("NCE"). For the purposes of this provision an NCE is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA or 505(b)(2) NDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of exclusivity if an NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication. Three-year exclusivity would be available for a drug product that contains a previously approved active moiety, provided the statutory requirement for a new clinical investigation is satisfied. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs or 505(b)(2) NDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product; rather this three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving follow-on applications for drugs containing the original active agent.

The FDA typically makes decisions about awards of data exclusivity shortly before an original NDA or efficacy supplement is approved. Five-year and three-year exclusivity also will not delay the submission or approval of a traditional NDA filed under Section 505(b)(1) of the FDCA. However, an applicant submitting a traditional NDA would be required to either conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Patent Term Extension

Depending upon the timing, duration and specifics of FDA approval of our drug candidate SB 11285 or any future drug candidates, some of our U.S. patents may be eligible for limited patent term extension under other provisions of the Hatch-Waxman Amendments. These patent term extensions permit a patent restoration term of up to five years as compensation for any patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of an NDA, plus the time between the submission

date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension, and the extension must be applied for prior to expiration of the patent. The United States Patent and Trademark Office ("USPTO") in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Coverage, Pricing, and Reimbursement

In both domestic and foreign markets, sales of any products for which we may receive regulatory approval will depend in part upon the availability of coverage and adequate reimbursement from third-party payors. Coverage also may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. In the United States, such third-party payors include government health programs, such as Medicare and Medicaid, private health insurers and managed care providers and other organizations. Coverage decisions may depend upon clinical and economic standards that disfavor new drug and biological products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Assuming coverage is granted, the reimbursement rates paid for covered products might not be adequate and eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Even if favorable coverage status and adequate reimbursement rates are attained, less favorable coverage policies and reimbursement rates may be implemented in the future. The marketability of any products for which we may receive regulatory approval for commercial sale may suffer if the government and other third-party payors fail to provide coverage and adequate reimbursement to allow us to sell such products on a competitive and profitable basis. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs and biologics. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. For example, under these circumstances, physicians may limit how much or under what circumstances they will prescribe or administer our future therapeutic products and patients may decline to purchase such products. This, in turn, could affect our ability to successfully commercialize our future therapeutic products and impact our profitability, results of operations, financial condition, and future success.

The market for any product candidates for which we may receive regulatory approval in the United States will depend significantly on the degree to which these products are listed on third-party payors' drug formularies or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included on such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug or biologic on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent, biosimilar product, or other alternative is available. In addition, no uniform coverage and reimbursement policy exists, and coverage and reimbursement can differ significantly from payor to payor. As such, one third-party payor's determination to provide coverage does not assure that other third-party payors will also provide coverage. Third-party payors often rely on Medicare coverage policy and payment limitations in setting their own reimbursement rates but also have their own methods to individually establish coverage and reimbursement policies. As a result, obtaining coverage and adequate reimbursement can be a time-consuming and costly process. We may be required to provide scientific and clinical support for the use of any of its approved biological products to each third-party payor separately with no assurance that approval would be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our future therapeutic products. We cannot be certain that our product candidates will be considered cost-effective by any private or government payors. This process could delay the market acceptance of any product candidates for which we may receive approval and could have a negative effect on our future revenues and operating results.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some countries, the pricing of

prescription pharmaceuticals is subject to government control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and adequate reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. Historically, therapeutic candidates launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

Additionally, the containment of healthcare costs has become a priority of federal and state governments and the prices of therapeutics have been a focus in this effort. The United States government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic and biosimilar products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our future net revenue and operating results. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement for the pharmaceutical or biological products apply to companion diagnostics.

Anti-Kickback, False Claims, Physician Payments Sunshine Acts and Other U.S. Healthcare Laws

In addition to FDA restrictions on marketing, several other types of U.S. state and federal laws are relevant to our current and future business operations, including broadly applicable fraud and abuse and other healthcare laws, including the anti-kickback and false claims laws, privacy and security laws and transparency laws. We are subject to these laws or will become subject to them in the future, and they may affect our business.

The U.S. federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for an item of service, or the purchase, lease, order or recommendation of any good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. The federal Anti-Kickback Statute is subject to evolving interpretations. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, formulary managers and other individuals and entities on the other hand, and the government has enforced the federal Anti-Kickback Statute to reach large settlements with healthcare companies based on sham consulting and other financial arrangements with physicians. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act, described below. There are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions; however, the exceptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exception or safe harbor may be subject to scrutiny. Moreover, in November 2020, the U.S. Department of Health and Human Services (“HHS”) finalized significant changes to the regulations implementing the Anti-Kickback Statute, as well as the Physician Self-Referral Law (Stark Law) and the civil monetary penalty rules regarding beneficiary inducements, with the goal of offering the healthcare industry more flexibility and reducing the regulatory burden associated with those fraud and abuse laws, particularly with respect to value-based arrangements among industry participants. As noted below in the section called “U.S. Healthcare Reform,” however, those final rules may be potentially overturned under the Congressional Review Act following the change in control of the legislative and executive branches in January 2021.

The federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalty laws, prohibit, among other things, any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to the U.S. government, or knowingly making, or causing to be made or

used, a false record or statement material to a false or fraudulent claim to the U.S. government, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government. Actions under these laws may be brought by the Attorney General or as a *qui tam* action by a private individual in the name of the government. Many pharmaceutical and other healthcare companies have faced investigations and lawsuits, including those brought by individuals through *qui tam* actions, for a variety of allegedly improper promotional and marketing activities, including inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates; providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees and other benefits to physicians to induce them to prescribe products; or engaging in promotion for "off-label" uses.

The Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations ("HIPAA"), created new federal, civil and criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a criminal violation of these laws. HIPAA also imposes obligations on certain covered entity healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. The 2009 amendments to HIPAA made the law's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. The amendments also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions.

The Physician Payments Sunshine Act, enacted as part of the Affordable Care Act in 2010 and implemented by HHS as the Open Payments Program, among other things, requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to track payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, chiropractors and, beginning in 2022 for payments and other transfers of value provided in the previous year, certain advanced non-physician healthcare practitioners) and teaching hospitals, as well as physician ownership and investment interests held by physicians and their immediate family members, and to publicly report such data to HHS. Manufacturers subject to the Open Payments Program must submit a report on or before the 90th day of each calendar year disclosing reportable payments made in the previous calendar year.

There are also analogous state laws and regulations, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers or that apply regardless of payor. Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual healthcare providers in those states. Some of these states also prohibit certain marketing related activities including the provision of gifts, meals, or other items to certain healthcare providers. Some states also require pharmaceutical companies to implement compliance programs or marketing codes and report information on the pricing of certain drugs. Certain state and local laws also require the registration of pharmaceutical sales representatives, and newly

emerging state that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory exemptions, it is possible that some of our future business activities could be subject to challenge under one or more of such laws. If our operations were found to be in violation of any of the federal or state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including significant criminal, civil monetary penalties, damages, disgorgement, fines, imprisonment, exclusion from participation in government programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private "qui tam" actions brought by individual whistleblowers in the name of the government, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

To the extent that any of our products are in the future sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

U.S. Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our product candidates profitably, even if we are approved for sale. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

In March 2010, the Affordable Care Act ("ACA"), was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjected biological products to potential competition by lower-cost biosimilars, created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Members of the U.S. Congress have expressed intent to pass legislation or adopt executive orders to fundamentally change or repeal parts of the ACA, and since its enactment, there have been judicial and Congressional challenges to the law, and as a result certain sections have not been fully implemented or effectively repealed. In addition, the Tax Cuts and Jobs Act, repealed, effective January 1, 2019 (the "TCJA"), the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In December 2018, a federal district court in Texas ruled the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. In December 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the lower court to determine whether other reforms enacted as part of

the ACA but not specifically related to the individual mandate or health insurance, including the provisions comprising the BPCIA, could be severed from the rest of the ACA so as not to be declared invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case and allocated one hour for oral arguments, which occurred on November 10, 2020. A decision from the Supreme Court is expected to be issued in spring 2021. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. F-star will continue to evaluate the effect that the ACA and its possible repeal and replacement has on the biopharmaceutical industry. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on F-star's business.

Other legislative changes have been proposed and adopted in the United States since the ACA that affect health care expenditures. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect through 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") which was signed into law on March 27, 2020, designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030, in order to offset the added expense of the 2020 cancellation. The 2021 Consolidated Appropriations Act was subsequently signed into law on December 27, 2020 and extends the CARES Act suspension period to March 31, 2021.

Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Notably, on December 20, 2019, President Trump signed the Further Consolidated Appropriations Act for 2020 into law (P.L. 116-94) that includes a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 (the "CREATES Act"). The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic and biosimilar product developers access to samples of brand products. Because generic and biosimilar product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic and biosimilar products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic or biosimilar product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic and biosimilar product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on our future commercial products are unknown.

In recent years, HHS has solicited feedback on various measures intended to lower drug prices and reduce the out of pocket costs of drugs and implemented others under its existing authority. For example, in May 2019, HHS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified an HHS policy change that was effective January 1, 2019. As part of the Trump Administration's so-called Blueprint to lower drug prices, HHS and FDA also released on July 31, 2019 their Safe Importation Action Plan proposing two different pathways for the importation of foreign drug products. One pathway focuses on the importation of certain drugs from Canada, which required the agencies to go through notice-and-comment rulemaking, while the second pathway allows manufacturers to distribute their drugs manufactured abroad and was released as agency policy in an FDA guidance document first issued in December 2019. FDA's notice of proposed rulemaking to implement a system whereby state governmental entities could lawfully import and distribute prescription drugs sourced from Canada was released at the end of December 2019 and in September 2020, the rulemaking was finalized by FDA. Those new

regulations became effective on November 30, 2020, although the impact of such future programs is uncertain, in part because lawsuits have been filed challenging the government's authority to promulgate them. The final regulations may also be vulnerable to being overturned by a joint resolution of disapproval from Congress under the procedures set forth in the Congressional Review Act, which could be applied to regulatory actions taken by the Trump Administration on or after August 21, 2020 (*i.e.*, in the last 60 days of legislative session of the 116th Congress). Congress and the executive branch have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs, making this area subject to ongoing uncertainty.

In addition, on May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new product candidates that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its product candidates available to eligible patients as a result of the Right to Try Act, although in 2020 the FDA published a notice of proposed rulemaking that would require manufacturers who do so to make annual reports of those programs to FDA. However, the January 20, 2021 transition to a new Democrat-led presidential administration created new uncertainty for ongoing regulatory matters that were initiated during the Trump Administration's final year in office. Following his inauguration, President Biden took immediate steps to order a regulatory freeze on all pending substantive executive actions in order to permit incoming department and agency heads to review whether questions of fact, policy, and law may be implicated and to determine how to proceed. It remains to be seen whether the proposed rule for annual reporting under the Right to Try Act advances to the final rule stage.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers ("PBMs") and other members of the healthcare and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug, which could have an adverse effect on customers for our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates. Whether or not we

obtain FDA approval for a product candidate, we must obtain approval from the comparable regulatory authorities of foreign countries or economic areas, such as the European Union and the United Kingdom, before we may commence clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

In the European Union, for example, an application for a Clinical Trial Application ("CTA"), must be submitted to the competent national authority and an application made to an independent ethics committee in each country in which the trial is to be conducted, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements and a favorable ethics committee opinion has been issued, clinical trial development may proceed. A similar process applies in the United Kingdom.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with cGCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. To obtain regulatory approval of an investigational drug or biological product under EU regulatory systems, we must submit a marketing authorization application either under the so-called centralized or national authorization procedures.

Centralized procedure. The centralized procedure provides for the grant of a single marketing authorization by the European Commission following a favorable opinion by the EMA that is valid in all EU member states, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products and products with a new active substance indicated for the treatment of specified diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases, other immune dysfunctions and viral diseases. The centralized procedure is optional for other products that represent a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of patients in the EU, or which contain a new active substance for indications other than those specified to be compulsory.

Following its departure from the European Union and the expiration of the transitional period, the United Kingdom recently adopted a decentralized and mutual recognition reliance procedure for marketing authorizations that allows the United Kingdom's clinical trial regulator, the MHRA, to consider marketing authorizations granted in the European Union or the three additional European Economic Area countries. However, additional requests for information may arise and additional time may be required with respect to applications for marketing authorizations in the United Kingdom using these procedures. For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with cGCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we or our potential collaborators fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

We are also subject to privacy laws in the jurisdictions in which we are established or in which we sell or market our products or run clinical trials. For example, we and our EU-based subsidiaries are subject to Regulation (EU)

2016/679, the General Data Protection Regulation ("GDPR"), in relation to our collection, control, processing and other use of personal data (i.e., data relating to an identifiable living individual) to the extent that the activities are by a data controller or processor established in the EU or where the individuals who are being monitored are based in the EU. We process personal data in relation to participants in our clinical trials, including the health and medical information of these participants. The GDPR is directly applicable in each EU member state, however, it provides that EU member states may introduce further conditions, including limitations which could limit our ability to collect, use and share personal data (including health and medical information), or could cause our compliance costs to increase, ultimately having an adverse impact on our business. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and implement policies as part of its mandated privacy governance framework. It also requires data controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used; imposes limitations on retention of personal data; clarifies that data protection rules apply in full to pseudonymized (i.e., key-coded) data pseudonymized (i.e., key-coded) data; introduces mandatory data breach notification requirements; and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. We are also subject to EU rules with respect to cross-border transfers of personal data out of the European Union and European Economic Area. We are subject to the supervision of local data protection authorities in those EU jurisdictions where we are established or otherwise subject to the GDPR. Fines for certain breaches of the GDPR can be significant: up to the greater of €20 million or 4% of total global annual turnover. In addition to the foregoing, a breach of the GDPR or other applicable privacy and data protection laws and regulations could result in regulatory investigations, reputational damage, orders to cease/ change our use of data, enforcement notices, or potential civil claims including class action type litigation. Following Brexit, the United Kingdom has incorporated the GDPR into its own data protection laws, and substantially equivalent risks also apply in the United Kingdom.

Employees and Human Capital

As of February 15, 2021, F-star had 75 full-time employees and four part-time employees, 73 are located in the United Kingdom and six in the United States. None of F-star's employees is subject to a collective bargaining agreement or represented by a trade or labor union. F-star considers its relationship with its employees to be good.

We are committed to developing therapies that can potentially benefit patients who are resistant to conventional cancer therapies or current therapies for other serious diseases. To that end, we recognize that our industry is specialized and dynamic, and a significant aspect of our success is our continued ability to execute our human capital strategy of attracting, engaging, developing and retaining highly skilled talent. There is fierce competition for highly skilled talent, particularly in the Boston, Massachusetts and Cambridge, United Kingdom areas, and we offer a robust set of benefits covering employees' physical, emotional and financial health, a strong company culture and initiatives aligned with our mission, vision, and values. We offer competitive compensation for our employees and strongly embrace pay for performance. We also strive to provide a collegial atmosphere where teamwork and collaboration are emphasized and valued. We have dedicated full-time professional employees who oversee all aspects of our human capital management process including talent acquisition. We have built a strong recruiting culture through a system of employee referrals and also closely partner with talent acquisition organizations with the objective to locate, attract and retain qualified experienced professionals. We are continuously exploring new markets as sources of talent.

Our Employee Handbook and Code of Business Conduct and Ethics clearly outlines our unwavering commitment to diversity and inclusion, where all employees are welcomed in an environment designed to make them feel comfortable, respected, and accepted regardless of their age, race, national origin, gender, religion, disability or sexual orientation. We have a set of policies explicitly setting forth our expectations for nondiscrimination and a harassment-free work environment. We are also a proud equal opportunity employer and cultivate a highly collaborative and entrepreneurial culture.

Facilities

Our principal offices occupy approximately 12,073 square feet of leased office, research and development and laboratory facility space in Cambridge, United Kingdom, pursuant to a lease agreement that expires in 2024. We also have additional lab space in Cambridge, UK. We have 2 properties in Hopkinton, USA, which are subleased to subtenants, and a virtual office agreement with Regus Management Group, LLC in Cambridge, Massachusetts, pursuant to a rolling lease agreement that expires in 2021. We believe that our current facilities are suitable and adequate to meet our current needs.

Corporate information

We were incorporated under the laws of the Commonwealth of Massachusetts as Spring Bank Technologies, Inc. on October 7, 2002. On May 12, 2008, we filed a certificate of incorporation in the State of Delaware and changed our state of incorporation to Delaware and our name to Spring Bank Pharmaceuticals, Inc. On November 20, 2020, we filed a certificate of amendment to the restated certificate of incorporation in the State of Delaware and changed our name to F-star Therapeutics, Inc. Our principal executive offices are located at Eddeva B920 Babraham Research Campus, Cambridge, United Kingdom CB22 3AT and our telephone number is 44-1223-497400.

Additional information

Our website address is www.F-star.com. The information contained in, or accessible through, our website does not constitute a part of this Annual Report on Form 10-K. We make available free of charge through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, as soon as reasonably practicable after we electronically file or furnish such materials to the Securities and Exchange Commission or the SEC. The SEC maintains a website that contains reports, proxy and information statements and other information regarding our filings at www.sec.gov. The information found on our website is not incorporated by reference into this Annual Report on Form 10-K or any other report we file with or furnish to the SEC.

Item 1A. Risk Factors.

We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. The risks described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time may also significantly impair our business operations. Our business could be harmed by any of these risks. Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all other information contained in this Annual Report on Form 10-K, including our condensed consolidated financial statements and the related notes, before making any decision to purchase our common stock. If any of the possible adverse events described below actually occurs, we may be unable to conduct our business as currently planned and our prospects, financial condition, operating results and cash flows could be materially harmed. In addition, the trading price of our common stock could decline due to the occurrence of any of the events described below, and you may lose all or part of your investment. In assessing these risks, you should refer to the other information contained in this Annual Report on Form 10-K, including our condensed consolidated financial statements and related notes.

Summary Risk Factors

We are subject to a number of risks that if realized could affect our business, financial condition, results of operations and cash flows. As a clinical stage company, certain elements of risk are inherent to our business. Accordingly, we encounter risks as part of the normal course of our business. Some of the more significant challenges and risks include the following:

- Uncertainty regarding future revenue and access to funding.
    - We are a clinical-stage biopharmaceutical company that currently generates no revenue from sales of any products, and we may never be able to develop or commercialize a drug or biologic product candidate. Even if we receive approval to market one or more products, we may never become profitable if we are unable to establish market acceptance, adequate market share or reimbursement from third-party payors. Additionally, if we receive approval, we expect our expenses to increase significantly in order to successfully launch such approved product candidate and such increases may not be commercially feasible. Further, if we cannot generate revenue from the sale of any approved products, we may never become profitable. We have also concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least twelve months from the issuance date of the financial statements.
- Clinical trial delays, adverse events, and/or clinical trial results may affect our business adversely.
    - Clinical development is expensive, time consuming and involves significant risk. If there is a failure of one or more of our clinical trials, at any stage of development, or if we experience serious adverse events, such failure may lead to additional costs to us or impair our ability to generate revenue. In addition, many of the factors, including the incidence of serious adverse events, that cause or lead to a delay in the commencement or completion of a clinical trial may also lead to the denial of marketing approval for our product candidates, which would lead to material harm to our business.
- We rely on third parties to manage our clinical programs, manufacture our product candidates and perform other services.
    - We rely on third-party vendors for key components of the development of our product candidates, including the manufacturing, management of clinical trials and other critical services. If such third-party vendors fail to comply with applicable laws, regulations or guidelines or are unable to obtain the materials needed for the manufacture of our product candidates, we may have a disruption in our clinical trials and potentially, commercial sale of a future approved product. We may not be able to manufacture product candidates or there may be substantial technical or

logistical challenges to supporting manufacturing demand for product candidates either by us or by our third-party manufacturers. Additionally, as we rely upon these vendors to perform release testing on our product candidate prior to delivery to subjects in our clinical trials or patients being treated with our product candidates, if approved in the future, such subjects or patients could be put at risk for serious harm, and we may face damaging product liability suits.

- We are subject to substantial regulation. As a biopharmaceutical company, we are subject to extensive regulation by government and regulatory agencies, such as the FDA and the EMA, among others. We may not receive the governmental approvals needed to market and commercialize our product candidates, which could have a material adverse effect on our financial condition, operations and prospects. The FDA and comparable foreign regulatory authorities have limited experience with mAb^2 products like our product candidates, which may increase the uncertainty surrounding as well as the expenses involved in the regulatory approval process for our product candidates. Such delays, unexpected costs or failure to obtain regulatory approval to market our product candidates could harm our ability to generate product revenue and our business, financial condition, results or operations and prospects may be harmed. Even if we obtain regulatory approval for a product, maintaining such compliance with regulatory requirements will result in additional expenses to us, which may be difficult to maintain.
- We are reliant on our intellectual property and are subject to the risk that we will not be able to protect our intellectual property rights. We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect our intellectual property related to our technologies and product candidates. Our commercial success depends on our ability to obtain, maintain and enforce patent and other intellectual property protections for our current and future technologies and product candidates. If we are unable to do so, our business may be materially harmed, our ability to commercialize our product candidates may be limited and our profitability may be delayed or may never occur.
- We depend on third party licensing or collaboration agreements. Our business strategy, along with our short- and long-term operating results depend in part on our ability to execute on existing strategic collaborations, including those with Ares Trading S.A, an affiliate of Merck KGaA, Darmstadt, Germany and Denali Therapeutics, and to license or partner with new strategic partners. If disputes arise between us and our partners in such agreements, there may be increased costs due to related litigation or if we decide to fund such programs ourselves. Disputes with partners may lead to substantial delays or possible termination of such agreements or related clinical trials and the need to seek a new partner for the development or commercialization of such product candidate. In addition, if commercialization collaboration partners do not commit sufficient resources to commercialize our future product candidates, and if we are unable to develop the necessary marketing and sales capabilities on our own, we will be unable to generate sufficient product revenue to sustain or grow our business.

- We are subject to substantial competition.
  - We compete with large pharmaceutical companies that have access to significant capital and materially greater manufacturing, marketing, research and drug development resources. We also compete with specialty pharmaceutical companies and biotechnology companies, including but not limited to, such as AstraZeneca plc, BMS, Eli Lilly and Company, MSD, Merck KGaA, Darmstadt, Germany, Novartis, Pfizer, Inc., Genentech, Inc., a subsidiary of the F. Hoffmann-La Roche AG Group and Sanofi, among others, as well as, universities and other research institutions worldwide that are developing drug or biological products for the same indications as us that could be more effective or less costly than our product candidates, which may render our candidates obsolete and noncompetitive.

- We have material weaknesses in our internal control over financial reporting.
    - We will need to hire additional qualified accounting personnel in order to remediate these material weaknesses in our internal control over financial reporting, and we will need to expend any additional resources and efforts that may be necessary to establish and to maintain the effectiveness of our internal control over financial reporting and our disclosure controls and procedures.

o We are vulnerable to disruptions and volatility in the financial markets.

- We are reliant in part on the financial markets to finance our future capital needs through public equity offerings, debt financings and other funding arrangements. Disruptions and volatility in the financial markets can have a material adverse effect on our ability to access capital and liquidity on acceptable financial terms. Negative and fluctuating economic conditions may present challenges in us obtaining additional capital needed to fund our operations. If we do not obtain funding on a timely basis and on acceptable terms, we may need to delay or discontinue one or more of our programs or the commercialization of our product candidates.

- We and others in our industry face cybersecurity risks.
    - We take protective measures and monitor and develop our systems continuously to protect our technology infrastructure and sensitive data, such as personally identifiable information about our employees and intellectual property, from cyberattacks. However, cybersecurity risks continue to increase for our industry, including for our third party vendors, who may hold some of our data, and the proliferation of new technologies and the increased sophistication and activities of the actors behind such attacks present risks for compromised or lost data, which could result in substantial costs and harm to our reputation as well as delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce such data.

The above list is not exhaustive, and we face additional challenges and risks. Please carefully consider all of the information in this Form 10-K including matters set forth in this “Risk Factors” section.

Risks Related to our Financial Position and Capital Requirements

We are a clinical-stage immuno-oncology company and have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

We are a clinical-stage immuno-oncology company with a limited operating history. We incurred net losses of $25.6 million for the year ended December 31, 2020 and $23.0 million for the year ended December 31, 2019. As of December 31, 2020, we had an accumulated loss of $47.2 million. Our losses have resulted principally from expenses incurred in research and development, preclinical testing and clinical development of our therapeutic product candidates as well as expenses incurred for research programs and from general and administrative costs associated with our operations. We expect to continue to incur significant and increasing operating losses for the foreseeable future as we continue our clinical trial plans, research and development efforts and seeks to obtain regulatory approval and commercialization of our tetravalent bispecific antibody (“mAb2”) product candidates, and New Chemical entity (NCE) drug product candidates like SB 11285, and we do not know whether or when we will become profitable. We have concluded that substantial doubt exists about our ability to continue as a going concern for a period of at least twelve months from the issuance date of the financial statements. Our losses, among other things, will continue to cause our working capital and shareholders’ equity to decrease. We anticipate that our expenses will increase substantially if and as we:

- continue to develop and conduct clinical trials for our current product candidates, FS118, FS120, FS222 and SB 11285;
- continue the research and development of our product candidates, including completing preclinical studies;
- discover and develop additional mAb^2 product candidates and makes further investments in its modular antibody technology platform;

- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities, whether alone or with third parties, to commercialize any product candidates for which we may obtain regulatory approval, if any;
- maintain, expand and protect our intellectual property portfolio, including litigation costs associated with defending against alleged patent infringement claims;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts;
- expand our operations in the United States, Europe and other geographies; and
- incur additional legal, accounting and other expenses associated with operating as a public company.

To date, we have funded our operations through private placements of equity securities and upfront and milestone payments and expense reimbursement payments received from our collaborators. We have invested substantially all of our financial resources and efforts to developing our mAb^2 product candidates in immuno-oncology, building our intellectual property portfolio, developing its supply chain, conducting business planning, licensing our technology to our collaborators, raising capital and providing general and administrative support for these operations. We do not currently have any approved products and has never generated any revenue from product sales.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our mAb^2 product candidates supportive of product approval, discovering and developing additional mAb^2 or small-molecule drug product candidates, obtaining regulatory approval for any product candidates that successfully complete clinical trials, establishing manufacturing and marketing capabilities and ultimately selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve or maintain profitability. Even if one or more of the mAb^2 product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond current expectations if we are required by the FDA, the EMA or other comparable foreign regulatory agencies to perform clinical trials or studies in addition to those that we currently anticipate. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could impair our ability to raise capital, expand our business, maintain our research and development efforts or continue our operations and you could lose some or all of your investment.

Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.

Since inception, we have invested most of our resources in developing our modular antibody technology platform, our mAb ^{2}technology and mAb^2 product candidates, building our intellectual property portfolio, conducting business planning, licensing our technology to our collaborators, raising capital and providing general and administrative support for these operations. Our most advanced mAb^2 product candidate, FS118, is currently being evaluated in a proof-of-concept Phase 2 trial in PD-1/PD-L1 acquired resistance head and neck cancer

patients. We have not yet demonstrated our ability to successfully complete Phase 2 clinical trials or any Phase 3 or other pivotal clinical trials, obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful product commercialization. In addition, given our limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors in achieving our business objectives. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or more experience developing product candidates.

We will need substantial additional funding in order to complete the development and commence commercialization of our product candidates. Failure to obtain this necessary capital at acceptable terms and when needed may force us to delay, reduce or eliminate out product development programs or commercialization efforts.

We expect our expenses to increase in connection with our ongoing activities, particularly as we complete the proof-of-concept Phase 2 clinical trial of FS118 and Phase 1 trials for FS120, FS222 and SB 11285 and initiate later-stage clinical development, and continues to research, develop and initiate clinical trials for any other product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution.

Furthermore, we have incurred, and expect to continue to incur, additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our product development programs or any future commercialization efforts.

The Company has incurred significant losses and has an accumulated deficit of $47.2 million as of December 31, 2020. We expect to incur substantial losses in the foreseeable future as we conduct and expand our research and development and pre-clinical and clinical activities. We do not expect that our $18.5M of existing cash as of December 31, 2020 will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months from the date of filing this Annual Report on Form 10K. We will need to raise additional capital to complete the development and commercialization of FS118, FS120, FS222, and SB 11285, if approved, and may also need to raise additional funds to pursue other development activities related to additional product candidates.

Our future capital requirements will depend on many factors, including:

- the cost, progress, results of the proof-of-concept Phase 2 clinical trial of FS118 and any later-stage clinical trials for this product candidate;
- the cost, progress, results of the Phase 1 clinical trials of FS120, FS222 and SB 11285 and any later-stage clinical trials for these product candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for any future product candidate;
- the number of potential new product candidates we identify and decides to develop;
- the cost of manufacturing drug supply for the clinical trials of our product candidates;
- the time and costs involved in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse clinical trial results with respect to any of our product candidates;
- the costs involved in growing our organization to the size and expertise needed to allow for the research, development and potential commercialization of our current or any future product candidates;

- fulfilling obligations under our existing collaboration agreements and the entry into new collaboration agreements;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- the cost of commercialization activities and costs involved in the creation of an effective sales, marketing and healthcare compliance organization for any product candidates we develop, if approved;
- the potential additional expenses attributable to adjusting our development plans (including any supply related matters) to the COVID-19 pandemic;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval; and
- the costs of operating as a public company.

Until we can generate sufficient product revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. Disruptions in the financial markets in general and the COVID-19 pandemic may make equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs.

Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. If adequate funds are not available on commercially acceptable terms when needed, we may be forced to delay, reduce or terminate the development or commercialization of all or part of our research programs product candidates or we may be unable to take advantage of future business opportunities.

Raising additional capital may cause dilution to holders of existing shareholders of us, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our operations with our existing cash and cash equivalents, including revenue from our collaborations. In order to further advance development of our product candidates, discover additional product candidates and pursue our other business objectives, however, we will need to seek additional funds.

We cannot guarantee that future financing will be available in sufficient amounts or on commercially reasonable terms, if at all. To the extent that we raise additional capital by issuing equity securities, our existing shareholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect our rights as a shareholder. Equity and debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming our shares, making investments, incurring additional debt, making capital expenditures or declaring dividends.

The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants therein, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely affect our ability to conduct our business.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any of our product

candidates, if approved, or be unable to expand its operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

We will need to hire additional qualified accounting personnel in order to remediate material weaknesses in our internal control over financial reporting, and we will need to expend any additional resources and efforts that may be necessary to establish and to maintain the effectiveness of our internal control over financial reporting and our disclosure controls and procedures.

Although we are not yet subject to the certification or attestation requirements of Section 404 of The Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), in connection with the preparation and audit of our financial statements for the year ended December 31, 2019, our management identified two material weaknesses related to our financial reporting process. PCAOB guidance regarding management's report on internal control over financial reporting defines a material weakness as a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

Management determined two material weaknesses that existed at December 31, 2019 and 2020. These material weaknesses relate to (i) the lack of formal policies and procedures and sufficient complement of personnel to implement effective segregation of duties and (ii) the lack of sufficient formality and evidence of controls over key reports and spreadsheets.

We have commenced measures to remediate these material weaknesses and have hired additional finance and accounting personnel with appropriate expertise to perform specific functions and allow for proper segregation of duties, design key controls and implement improved processes and internal controls, build our financial management and reporting infrastructure, and further develop and document our accounting policies and financial reporting procedures, including ongoing senior management review and audit committee oversight. We will continue to assess our finance and accounting staffing needs to remediate these material weaknesses.

There can be no assurance that we will be successful in pursuing these measures or that these measures will significantly improve or remediate the material weaknesses described above. There is also no assurance that we have identified all of our material weaknesses or that we will not in the future have additional material weaknesses. If we fail to remediate the material weaknesses or to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and our share price may decline as a result. We also could become subject to investigations by Nasdaq, the SEC or other regulatory authorities.

We believe our current cash and cash equivalents will be sufficient to fund our business only for a limited amount of time, and if we are not able to raise additional funds, we may be unable to continue as a going concern.

We expect our costs and expenses to increase as we continue to develop our product candidates and progress our current clinical programs and cost associated with being a public company.

Since our inception, we have incurred significant losses and had an accumulated deficit of $47.2 million as of December 31, 2020. We expect to incur substantial losses in the foreseeable future as we conduct and expand our research and development activities. As of March 30, 2021, the date of the approval and issuance of the consolidated financial statements, we do not expect our cash deposits will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 months, these conditions give rise to a substantial doubt over the company's ability to continue as a going concern.

We will be required to seek additional funding through public equity, private equity, debt financing, collaboration partnerships, or other sources. There are no assurances, however, that we will be successful in raising additional working capital, or if we are able to raise additional working capital, we may be unable to do so on commercially favorable terms. Our failure to raise capital or enter into other such arrangements if and when needed would have a negative impact on our business, results of operations and financial condition and our ability to develop our product candidates.

Pursuant to the requirements of Accounting Standard Codification (ASC) 205-40, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date of these financial statements, and (1) is probable that the plan will be effectively implemented within one year after the date the financial statements are issued, and (2) it is probable that the plan, when implemented, will mitigate the relevant condition or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date the financials are issued.

Certain elements of our operating plan to alleviate the condition that raise substantial doubt are outside of our control and cannot be included in management's evaluation under the requirements of Accounting Standard Codification (ASC) 205-40, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. Accordingly, the Company has concluded that substantial doubt exists about the Company's ability to continue as a going concern for a period of at least twelve months from the issuance date of the financial statements.

We may be subject to adverse legislative or regulatory tax changes that could negatively impact our financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the IRS and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our stockholders or us. In recent years, many such changes have been made and changes are likely to continue to occur in the future. We cannot predict whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided, which could result in an increase in our, or our stockholders', tax liability or require changes in the manner in which we operate in order to minimize increases in our tax liability.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in the ownership of its equity over a three year period), the corporation's ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income may be limited. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. As of December 31, 2020, we had federal net operating loss carryforwards of approximately $123.7 million, and our ability to utilize those net operating loss carryforwards could be limited by an "ownership change" as described above, which could result in increased tax liability to us. In addition, pursuant to the Tax Cuts and Jobs Act, we may not use U.S. federal net operating loss carry-forwards to reduce our taxable income in any year by more than 80%, and we may not carry back any net operating losses to prior years. These new rules apply regardless of the occurrence of an ownership change.

Risks Related to Development and Commercialization

If we are unable to advance our current or future product candidates through clinical trials, obtain marketing approval and ultimately commercialize any product candidates we develop, or if we experience significant delays in doing so, our business will be materially harmed.

We are early in our product candidate development efforts and have four product candidates in clinical development, each of which is still in early-stage clinical trials. We have invested substantially all of our efforts and financial resources in the development of our proprietary mAb^2 technology, identification of targets and preclinical development of our product candidates.

Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of the product candidates we develop, which may never occur. Our current product candidates, and any future product candidates we develop, will require additional preclinical and clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other jurisdictions, demonstrating cost effectiveness to pricing and reimbursement authorities in various jurisdictions, obtaining and securing sufficient manufacturing supply for both clinical development and commercial production, building of a commercial organization, and substantial investment and significant marketing efforts before we generate any revenues from any future product sales. Moreover, the success of our current and future product candidates will depend on several factors, including the following:

- successful and timely completion of preclinical studies, including *in vivo* animal studies if necessary, and human clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- receiving regulatory approvals or authorizations for conducting our planned clinical trials or future clinical trials;
- initiation and successful patient enrollment in and completion of clinical trials on a timely basis;
- safety, tolerability and efficacy profiles that are satisfactory to the FDA, the EMA or any other comparable foreign regulatory authority for a product to receive marketing approval;
- timely receipt of marketing approvals for our product candidates from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments made to applicable regulatory authorities;
- establishing and scaling up, either alone or with third-party manufacturers, manufacturing capabilities of clinical supply for our clinical trials and subsequently for commercial manufacturing, if any product candidates are approved;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates, the latter only if they receive marketing approval, both in the United States and internationally;
- successfully scaling a sales and marketing organization and launching commercial sales of our product candidates, if approved;
- acceptance of our product candidates' benefits and uses, if approved, by patients, the medical community and third-party payors;
- maintaining a continued acceptable safety profile of our product candidates following marketing approval and commercial launch;
- effectively competing with companies developing and commercializing other therapies in the same indications targeted by our product candidates;

- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors for any approved products; and
- enforcing and defending intellectual property rights and claims.

If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize any product candidates we develop, which would materially harm our business. If we do not receive marketing approvals for our current and future product candidates, we may not be able to continue our operations.

All of our product candidates are in early clinical development. Clinical trials are difficult to design and implement, and they involve a lengthy and expensive process with uncertain outcomes. We may experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current and future product candidates.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful.

To date, we have not completed any clinical trials required for the approval of any of our product candidates. Although FS118 is currently being evaluated in a Phase 2 proof-of-concept trial and FS120, FS222 and SB 11285 are currently being evaluated in Phase 1 trials, we may experience delays in our ongoing clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll study subjects on time, have sufficient drug supply of our product candidates in order to be completed timely or be completed on schedule, if at all. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to complete the trials successfully and ultimately to receive marketing approval or to commercialize the product candidates we are developing, including:

- delays in or failure to obtain regulatory approval or clearance to commence a clinical trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- delays or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on appropriate clinical trial designs;
- delays in or failure to reach agreement on acceptable terms with prospective contract research organizations (“CROs”), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- inability, delays or failure in identifying and maintaining a sufficient number of clinical trial sites, many of which may already be engaged in other clinical research programs;
- delays in or failure to obtain ethics committee/institutional review board (“EC/IRB”) approval at each site participating in the trial;
- delays in or failure to recruit a sufficient number of suitable subjects to participate in a trial;
- failure to have participants complete a trial or return for post-treatment follow-up, or other inability to monitor patients adequately during or after treatment;
- clinical sites or clinical investigators deviating from trial protocol or dropping out of a trial;
- delays in adding new clinical trial sites;
- failure to manufacture sufficient quantities of a product candidate for use in clinical trials in a timely manner;

- delay or failure in developing and validating companion diagnostics, if they are deemed necessary, on a timely basis;
- safety or tolerability concerns that could cause us or our collaborators, as applicable, to suspend or terminate a trial if we or our collaborators find that the participants are being exposed to unacceptable health risks;
- changes in regulatory requirements, policies and guidelines;
- failure of our third-party research contractors, including clinical sites and investigators, to comply with regulatory requirements applicable to the trial, including GCPs, or to meet their contractual obligations to us in a timely manner, or at all;
- delays in establishing the appropriate dosage levels for a particular product candidate through clinical trials;
- the quality or stability of the product candidate falling below acceptable standards; and
- business interruptions resulting from pandemics, such as the ongoing COVID-19 pandemic, or geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

We could encounter delays if we elect to suspend or terminate a clinical trial, or if a trial is suspended or terminated by the EC/IRBs of the institutions in which such trials are being conducted, or by the FDA, the EMA, or other comparable foreign regulatory authorities, or if a trial is recommended for suspension or termination by the Safety Review Committee ("SRC"), Data Review Committee ("DRC"), or Data Safety Monitoring Board ("DSMB"), for such trial. Any such authorities may impose such a suspension or termination of ongoing human subjects research due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, the EMA, or other comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, including those relating to the class to which our product candidates belong, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or if we terminate, any clinical trial of a product candidate, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed or may become impossible. In addition, any delays in completing clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence future product sales and generate revenues.

Moreover, if we make changes to our product candidates, we may need to conduct additional scientific studies to bridge our modified product candidates to earlier versions, which could delay our clinical development plans or future marketing approval for our product candidates. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates, if approved for marketing, and impair our ability to commercialize any such product candidates.

Any of these occurrences may harm our business, reputation, financial condition and results of operations significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval for our product candidates or result in the cessation of development of our product candidates.

Our clinical trials may fail to demonstrate adequately the safety and efficacy of any of our product candidates, which would prevent or delay regulatory approval and commercialization.

We currently have no products approved for sale and cannot guarantee that we will ever have marketable products. To obtain the requisite regulatory approvals to market and sell any of our product candidates, including

FS118, FS120, FS222, SB 11285 and any other future product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our products are safe and effective in humans for their intended use or uses. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful. Further, the process of obtaining regulatory approval to market therapeutic products like our product candidates is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications, patient population and regulatory agency considering the product's marketing application. Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our potential future collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA, the EMA or other comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses.

Clinical trials that we conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be delayed in obtaining marketing approval, if at all.

Even if the trials are successfully completed, clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA, the EMA, or other comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit a product candidate for marketing approval. We cannot guarantee that the FDA, the EMA or other comparable foreign regulatory authorities will view our product candidates as being effective and having a favorable benefit-risk profile even if positive results are observed in clinical trials. To the extent that the results of the trials are not satisfactory to the FDA, the EMA or other comparable foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

The results of preclinical studies and early-stage clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Initial success in our ongoing clinical trials may not be indicative of results obtained when these trials are completed or in later-stage trials.

Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Furthermore, there can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for drugs proceeding through clinical trials. Many companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain regulatory authority approval. Any such setbacks in our clinical development could have a material adverse effect on our business, financial condition and results of operations.

Additionally, some of the clinical trials we conduct may include open-label trials conducted at a limited number of clinical sites on a limited number of patients. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved product or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Moreover, patients selected for early-stage clinical trials often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, topline or preliminary data from our clinical trials. Preliminary and interim data from our clinical trials may change as more patient data become available. Preliminary or interim data from our clinical trials are not necessarily predictive of final results. Preliminary and interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, more patient data become available, and we issue our final clinical trial report. Interim, topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary, topline and interim data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the interim data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or therapeutic product, if any, and us in general. In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular therapeutic product, if any, product candidate or our business. If the preliminary and interim data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Our product candidates may have serious adverse, undesirable or unacceptable side effects that may delay or prevent marketing approval. If such side effects are identified during the development of our product candidates or following approval we may need to abandon development of such product candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval.

Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label should the candidate be approved for marketing or the delay or denial of regulatory approval by the FDA, the EMA or other comparable foreign regulatory authorities. While the data collected on our product candidates in our preclinical studies, and the early clinical trial experience with FS118 and SB 11285 to date, suggest that the candidates have

generally been well-tolerated from a risk-benefit perspective, the results from future preclinical studies and clinical trials, including of our other product candidates, may not support this conclusion.

The results of our ongoing proof-of-concept Phase 2 clinical trial of FS118 and Phase 1 trials for FS120, FS222 and SB 11285 and future clinical trials of these and other product candidates may show that our product candidates cause undesirable or unacceptable side effects or even death. In such an event, our trials could be suspended or terminated and the FDA, the EMA or other comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Further, because the majority of our current product candidates are based on our modular antibody technology platform and our mAb^2 technology, any adverse safety or efficacy findings related to any mAb ^{2} product candidate or preclinical program may adversely impact the viability of our other mAb^2 product candidates or preclinical programs. Any of these occurrences may harm our business, reputation, financial condition and results of operations significantly.

Additionally, if any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such a product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product and require our approved product to be taken off the market, through a recall or other action;
- regulatory authorities may require the addition of labeling statements or specific warnings, such as a “black box” warning or a contraindication, to the product’s prescribing information, or require field alerts to be sent to physicians and pharmacies;
- regulatory authorities may require a medication guide explaining the risks of such side effects to be distributed to patients, or that we are to implement a risk evaluation and mitigation strategy to ensure that the benefits of the product outweigh its risks (such as through a REMS in the United States that may include a restricted distribution program or educational programs for prescribers);
- we may be required to change the way the product is administered;
- we may be required to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us, our collaborators or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our mAb^2 product candidates, if approved.

We may find it difficult to enroll subjects in our clinical trials, which could delay or prevent us from proceeding with clinical trials of our product candidates.

Identifying and qualifying study subjects to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on our ability to recruit eligible subjects to participate as well as the completion of required follow-up evaluations. Patients and healthy volunteers may be unwilling to participate in our clinical trials because of negative publicity from adverse events related to novel therapeutic approaches, competitive clinical trials for similar patient populations, the existence of current treatments or for

other reasons including due to concerns posed by the COVID-19 pandemic. Enrollment risks are heightened with respect to indications that we may target in the future that may be rare or orphan diseases, which may limit the pool of patients that may be enrolled in our planned clinical trials. Any delays related to subject enrollment could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our product candidates or termination of the clinical trials altogether. We may not be able to identify, recruit and enroll a sufficient number of subjects, or those with the required or desired characteristics, to complete our clinical trials in a timely manner. Enrollment and trial completion is affected by many factors, including the:

- size and nature of the patient population and process for identifying potential study subjects;
- proximity and availability of clinical trial sites for prospective participants;
- the extent of we and our collaborators' efforts to facilitate timely enrollment in clinical trials;
- eligibility and exclusion criteria for the trial;
- design of the clinical trial;
- safety profile, to date, of the product candidate under study;
- perceived risks and benefits of the product candidate under study;
- perceived risks and benefits of our approach to treatment of diseases;
- competition with other companies for clinical sites and qualified clinical investigators;
- severity of the disease under investigation;
- degree of progression of the subject's disease at the time of enrollment;
- ability to obtain and maintain the study subject's informed consent;
- risk that enrolled subjects will drop out before completion of the trial;
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- patient referral practices of physicians; and
- ability to adequately monitor subjects during and after investigational treatment.

We face significant competition for our drug discovery and development efforts, and if we do not compete effectively, our commercial opportunities will be reduced or eliminated.

We compete in the segments of the biotechnology, pharmaceutical and other related markets that develop immuno-oncology therapies, and the market for biopharmaceutical products is highly competitive. Our competitors include many established pharmaceutical companies, biotechnology companies, universities and other research or commercial institutions, many of which have substantially greater financial, research and development resources than us. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, recruiting patients, obtaining regulatory approvals, manufacturing and marketing pharmaceutical products. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, the development of our product candidates. The fields in which **we** operate are characterized by rapid technological change and innovation.

There are many other companies that have commercialized and/or are developing immuno-oncology therapies for cancer including large biotechnology and pharmaceutical companies, such as AstraZeneca plc

("AstraZeneca"), BMS, Eli Lilly and Company ("Eli Lilly"), MSD, Merck KGaA , Darmstadt, Germany ("EMD Serono"), Novartis, Pfizer, Inc. ("Pfizer"), Genentech, Inc. ("Genentech"), a subsidiary of the F. Hoffmann-La Roche AG Group ("Roche") and Sanofi. A number of companies, not limited to those above, are attempting to combine immuno-oncology antibody therapies in order to modulate two cancer pathways simultaneously. Others have developed bispecific antibodies or bispecific fusion proteins in order to leverage the effect of a combination of single-target traditional monoclonal antibodies, which we refer to as traditional antibodies, in a single molecule.

With respect to our mAb 2 bispecific antibody pipeline, we are aware of several competitors using other technology methods to create bispecific antibodies to treat a variety of cancer types, including, but not limited to: Genmab A/S, Inhibrx, MacroGenics, Merus, Pieris Pharmaceuticals, Hoffmann-La Roche, Shattuck Labs and Xencor, Inc.

With respect to our lead mAb 2 product candidate, FS118, we are aware of other competing molecules targeting LAG-3 and PD-1/PD-L1 receptors. Companies pursuing a bispecific molecule directed against LAG-3 and PD-1/PD-L1 in different phases of clinical development include, but are not limited to: Epimab, MacroGenics and Hoffmann-La Roche. We are also aware of other companies pursuing a combination of two traditional antibodies in different phases of clinical development, with one targeting PD-1/PD-L1, and one targeting LAG-3, which include but are not limited to: BMS, C.H. Boehringer Sohn AG & Co. KG and MSD.

With respect to our second mAb 2 product candidate, FS120, we are aware of other companies pursuing bispecific antibodies targeting OX40 and CD137, which include but are not limited to Aptevo Therapeutics. We are also aware that Pfizer has ongoing clinical studies evaluating a combination of CD137 plus OX40 traditional antibodies.

With respect to our third mAb 2 product candidate, FS222, we are aware of other companies pursuing bispecific antibodies targeting PD-L1 and CD137 in clinical development, which include but are not limited to: Genmab/BioNTech SE, Inhibrx/Elpiscience, Merus/Incyte and Numab Therapeutics AG/CStone Pharmaceuticals. We are also aware of other companies that are pursuing a combination of two traditional antibodies in clinical development, with one targeting PD-1/PD-L1, and one targeting CD137, which include but are not limited to: Adagene, BMS, Lyvgen Biopharma (Suzhou)/MSD, Pfizer and Hoffmann-La Roche.

With respect to our fourth product candidate, SB 11285, we are aware of other companies pursuing a second generation, intravenously administered STING agonist, in clinical development, which include but are not limited to: GSK, Millennium Therapeutics/Takeda and Silicon Therapeutics.

We anticipate that we will continue to face increasing competition as new treatments enter the market and advanced technologies become available. There can be no assurance that our competitors are not currently developing, or will not in the future develop, products that are equally or more effective or are safer or are more economically attractive than any of our current or future product candidates, or platforms and technology that are superior to our modular antibody technology platform and our mAb2 technology. Competing products or technology platforms may gain faster or greater approval or market acceptance than our products, if any, or modular antibody technology platform and medical advances or rapid technological development by competitors may result in our product candidates or modular antibody technology platform becoming non-competitive or obsolete before we are able to recover our research and development and commercialization expenses. If we, our product candidates or our modular antibody technology platform do not compete effectively, it may have a material adverse effect on our business, financial condition, and results of operations.

The regulatory approval processes of the FDA, the EMA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain marketing approval for a novel therapeutic product from the FDA, the EMA and other comparable foreign regulatory authorities is unpredictable but typically takes many years following the

commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, laws or regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for commercialization, of any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain that approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- The FDA, EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA or other comparable foreign regulatory authorities that a mAb[2] product candidate is safe, pure and potent or effective for its proposed indication(s) or that a small-molecule drug product candidate is safe and effective for its proposed indication(s);
- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA or other comparable foreign regulatory authorities in order to support approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, the EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a Biologics License Application ("BLA") or New Drug Application ("NDA"), to the FDA or other equivalent marketing authorization application submissions to obtain regulatory approval in the United States, the EU or elsewhere;
- upon review of our clinical trial sites and data, the FDA, EMA or comparable foreign regulatory authorities may find our record keeping or the record keeping of our clinical trial sites or investigators to be inadequate;
- the FDA, the EMA or other comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, the EMA or other comparable foreign regulatory authorities or the laws they enforce may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, financial condition and results of operations. The FDA, the EMA and other comparable foreign regulatory authorities have substantial discretion in the approval process and determining when or whether to grant regulatory approval will be obtained for any of our product candidates, and whether to impose any conditions on such marketing approvals as described below. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, the EMA or other comparable foreign regulatory authorities.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we requests, if any, they may grant approval contingent on the performance of costly post-marketing clinical trials, or they may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate or with restrictive risk mitigation measures or warning language or contraindications that make the

approved product more difficult or costly to commercialize. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

If we are required by the FDA to obtain approval of a companion diagnostic in connection with approval of a product candidate, and we do not obtain or face delays in obtaining FDA approval of a diagnostic device, we will not be able to commercialize the product candidate and our ability to generate revenue will be materially impaired.

According to current FDA policies, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product in an intent to treat indication, the FDA will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. Under the U.S. Federal Food, Drug, and Cosmetic Act, companion diagnostics are regulated as medical devices, and the FDA requires companion diagnostics intended to select the patients who likely will respond to cancer treatment to receive Premarket Approval ("PMA") before being commercially distribution. The PMA application process, including the gathering of analytical and prospective clinical data and the submission to and review by the FDA, is rigorous and requires the applicant to provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, performance, good manufacturing practices, and labeling. A PMA is not guaranteed and may take considerable time, and the FDA may ultimately respond to a PMA submission with a "not approvable" determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval. As a result, if we are required by the FDA to obtain approval of a companion diagnostic for a therapeutic product candidate, and we do not obtain or there are delays in obtaining FDA approval of such a diagnostic device, we may not be able to commercialize the product candidate on a timely basis or at all and our ability to generate revenue will be materially impaired.

Any product candidate for which F-star obtains marketing approval will be subject to extensive post-marketing regulatory requirements, which may result in significant additional expense, and could be subject to post-marketing restrictions or withdrawal from the market, and F-star or its partners may be subject to penalties for any failure to comply with regulatory requirements or if problems are discovered with a product after approval.

Our therapeutic product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with ongoing regulatory requirements or experiences unanticipated problems with any such approved prescription drug or biological products.

If the FDA, the EMA or other comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the therapeutic product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration, as well as continued compliance with current Good Manufacturing Practices ("cGMPs") by all facilities involved in the production of the approved therapeutic product and with compliance with Good Clinical Practices ("GCPs") by all collaborators in any clinical trials that we may conduct post-approval, each of which may result in significant expense. In addition, any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. The FDA, as well as its foreign regulatory counterparts, also have significant post-market authority, including the authority to require labeling changes based on new safety information.

Moreover, the FDA strictly regulates the promotional claims that may be made about prescription drug and biological products. In particular, a product may not be promoted for off-label uses that are not approved by the

FDA as reflected in the product's approved prescribing information and other FDA-approved product labeling. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses for prescription medical products. Further, if there are any modifications to the biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA/NDA or BLA/NDA supplement.

If there are changes in the application of legislation, regulations or regulatory policies, or if problems are discovered with a product or our manufacture of a product, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, regulatory authorities could take various actions against the therapeutic product or against F-star as the product's sponsor. These include imposing fines on us, imposing restrictions on the product or its manufacture and requiring a recall or other removal of the product from the market. The regulators could also suspend or withdraw our marketing authorizations, require us to conduct additional clinical trials or to submit additional applications for marketing authorization, or require safety updates to or otherwise change the product labeling for an approved therapeutic product. If any of these events occurs, our ability to sell such product may be impaired, and We may incur substantial additional expense to comply with regulatory requirements, which could materially adversely affect our business, financial condition and results of operations.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of biopharmaceutical products. Currently, we have no products that have been approved for commercial sale; however, the current and future use of product candidates by us and our collaborators in clinical trials, and the potential sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients who use the product, healthcare providers, pharmaceutical companies, our collaborators or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates. Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a product, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products due to negative public perception;
- injury to our reputation;
- withdrawal of clinical trial participants or difficulties in recruiting new trial participants;
- initiation of investigations by regulators;
- costs to defend or settle the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues from product sales; and
- the inability to commercialize any of our product candidates, if approved.

Although we believe it maintains adequate product liability insurance for our product candidates, it is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against it for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Should any of the events described above occur, this could have a material adverse effect on our business, financial condition and results of operations.

Due to our limited resources and access to capital, we must, and has in the past decided to, prioritize development of certain product candidates over other potential product candidates. These decisions may prove to have been wrong and may adversely affect our ability to develop our own programs, our attractiveness as a commercial partner and may ultimately have an impact on our commercial success.

Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each. Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular mAb^2 bispecific antibodies, product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities. Similarly, our decisions to delay, terminate or collaborate with third parties in respect of certain product development programs may also prove not to be optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the market potential of our product candidates or misreads trends in the biopharmaceutical industry our business, financial condition and results of operations could be materially adversely affected.

We may seek orphan drug designation for product candidates we develop, and we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity if a designed product candidate is ultimately approved.

As part of our business strategy, we may seek orphan drug designation for any product candidates we develop, and we may be unsuccessful in securing such a designation. Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act in the United States, the FDA may designate a drug or a biological product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards certain clinical trial costs, tax advantages and user-fee waivers.

Similarly, in Europe, the European Commission grants orphan designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an orphan designation application. Orphan designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in the EU and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug. In the EU, orphan designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

Generally, in the United States, if a drug or biologic with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug and the same orphan indication for that time period, except in limited circumstances. The applicable period is seven years in the United States. In addition, there is a potential to receive a six-month extension of orphan exclusivity if certain pediatric studies are conducted and the results are reported to the FDA in response to a Written Request for such studies under the Best Pharmaceuticals for Children Act.

In Europe, an approved orphan medicinal product is entitled to ten years of market exclusivity in all EU member states. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the ten-year period with the consent of the marketing authorization holder for the original orphan medicinal product or if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities of such product. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if the similar product is established to be safer, more effective or otherwise clinically superior to the original orphan medicinal product. After five years, an EU member state can request that the period of market exclusivity be reduced to six years if it can be demonstrated that the criteria for orphan designation no longer apply and the medicine is sufficiently profitable. The period of market exclusivity may be extended for an additional two years for medicines that have also complied with an agreed pediatric investigation plan ("PIP").

Similarly, even if we obtain orphan drug exclusivity for a product candidate that is approved for marketing in the U.S., such exclusivity may not effectively protect the product candidate from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off-label. Even after an orphan drug is approved, the FDA can subsequently approve the later drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we may seek orphan drug designation for applicable indications for our current and any future product candidates, we may never receive such designations.

Accordingly, even if we do receive such designations in the U.S. and/or in Europe, there is no guarantee that we will enjoy the benefits of those designations.

Our approach to the discovery and development of our therapeutic treatments is based on novel technologies that are unproven and may not result in marketable products.

We plan to develop a pipeline of mAb ^{2} product candidates using our modular antibody technology platform. We believe that mAb ^{2} product candidates identified with our modular antibody technology platform may offer an improved therapeutic approach by creating fully formed molecules using standard antibody production technology, thereby potentially improving the binding and biological response, and reducing any need for reassembly or other post-synthesis modifications.

However, we have not, nor to our knowledge has any other company, received regulatory approval for a therapeutic that uses tetravalent bispecific IgG1 antibody technology. We cannot be certain that our approach will lead to the development of approvable or marketable products. In addition, the FDA, the EMA or other comparable foreign regulatory agencies may lack experience in evaluating the safety and efficacy of products

based on our mAb^2 technology, which could result in a longer than expected regulatory review process, increase our expected development costs and delay or prevent commercialization of our mAb^2 product candidates.

We may not be successful in our efforts to utilize our modular antibody technology platform and mAb ^{2} technology to build a pipeline of additional mAb^2 product candidates. Failure to successfully identify, develop and commercialize additional products or mAb ^{2} product candidates could impair our ability to grow.

Although a substantial amount of our efforts will continue to focus on the preclinical studies and clinical testing and potential approval of the mAb^2 product candidates in our current pipeline, a key element of our long-term growth strategy is to identify, develop and market additional products and mAb^2 product candidates. Because We have limited financial and managerial resources, continuing to utilize our modular antibody technology platform and our mAb^2 technology to generate mAb ^{2} bispecific antibodies and identify mAb ^{2} product candidates with certain advantages, such as safety and potency, beyond what would be achieved with a combination of two traditional antibodies or bispecific antibodies, will require substantial additional technical, financial and human resources, whether or not any mAb^2 product candidates are ultimately identified. Our modular antibody technology platform may fail to generate mAb^2 bispecific antibodies that are suitable for further development, and we may fail to correctly identify future mAb^2 product candidates that have the potential to become successful products. We will need to continue to invest in improving and expanding our modular antibody technology platform and our mAb^2 technology, which will require scientific expertise and substantial resources.

We also have incorporated a novel technology of synthesizing cyclic dinucleotides for the generation of STING pathway targeting small-molecule drug product candidates, such as our current clinical candidate SB 11285. We cannot be certain that this approach will lead to the development of approvable or marketable products. In addition, the FDA, the EMA or other comparable foreign regulatory agencies may lack experience in evaluating the safety and efficacy of such products, which could result in a longer than expected regulatory review process, increase our expected development costs and delay or prevent commercialization of our product candidates. We may not be successful in our efforts to utilize our cyclic dinucleotide technology to build additional product candidates. Failure to successfully identify, develop and commercialize additional products or product candidates could impair our ability to grow.

All therapeutic product candidates are prone to risks of failure typical of biopharmaceutical product development, including the possibility that a product candidate may not be suitable for clinical development as a result of its harmful side effects, limited efficacy or other characteristics that indicate that it is unlikely to be a product that will receive approval by the FDA, the EMA and other comparable foreign regulatory authorities and achieve market acceptance. If we do not successfully develop and commercialize our mAb^2 biological product candidates or small-molecule STING agonist drug product candidates based upon our current platforms and technological approaches, we may not be able to obtain product or collaboration revenues in future periods, which would adversely affect our business, financial condition and results of operations.

Our product candidates that are successful in achieving marketing approval may face generic or biosimilar competition sooner than anticipated.

Even if we are successful in achieving regulatory approval to commercialize a product candidate for a specific indication ahead of our competitors, such an approved therapeutic candidate may face competition from generic or biosimilar products, as applicable.

In the United States, mAb ^{2} product candidates are regulated by the FDA as biological products and we intend to seek approval for these therapeutic candidates pursuant to the BLA pathway. The BPCIA created an abbreviated pathway for the FDA approval of biosimilar biological products based on a previously licensed innovator, or reference, biological product. Under the BPCIA, an application for a biosimilar biological product cannot be approved by the FDA until 12 years after the original reference biological product was approved under

a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our product candidates.

We believe that any of our mAb 2 product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity available to reference biological products. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our therapeutic candidates to be reference biological products pursuant to its interpretation of the exclusivity provisions of the BPCIA, potentially creating the opportunity for follow-on biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar product, once approved, will be substituted for any reference product in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing including whether a future competitor seeks an interchangeability designation for a biosimilar of a future approved biological products. Under the BPCIA as well as state pharmacy laws, only so-called “interchangeable” biosimilar products are considered substitutable for the reference biological product without the intervention of the healthcare provider who prescribed the original biological product. However, as with all prescribing decisions made in the context of a patient-provider relationship and a patient’s specific medical needs, healthcare providers are not restricted from prescribing biosimilar products in an off-label manner. In addition, a competitor could decide to forego the abbreviated approval pathway available for biosimilar products and to submit a full BLA for product licensure after completing its own preclinical studies and clinical trials. In such a situation, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its biological product as soon as it is approved.

In Europe, the European Commission has granted marketing authorizations for several biosimilar products pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In addition, companies may be developing biosimilar products in other countries that could compete with our products, if approved.

If competitors are able to obtain marketing approval for biosimilars referencing an approved our mAb 2 product candidates, if approved, our future products may become subject to competition from such biosimilars, whether or not they are designated as interchangeable, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which its product candidates may have received approval.

Further, our small-molecule drug product candidates such as SB 11285 are regulated by the FDA as drug products and would be subject to marketing approval by the FDA pursuant to an NDA submitted under Section 505(b)(1) of the FDCA. Even if we are successful in achieving regulatory approval to commercialize SB 11285 or a future drug product candidate, we may face competition from generic products earlier or more aggressively than anticipated, depending upon how well the future product performs in the United States prescription drug market. In addition to creating the 505(b)(2) NDA pathway that allows for follow-on applications relying on a reference drug product when some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference, the Hatch-Waxman Amendments to the FDCA authorized the FDA to approve generic drugs that are the same as drugs previously approved for marketing under the NDA provisions of the statute pursuant to abbreviated new drug applications, or ANDAs. An ANDA relies on the preclinical and clinical testing conducted for a previously approved reference listed drug (“RLD”) and must demonstrate to the FDA that the generic drug product is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug and also that it is “bioequivalent” to the RLD. The FDA is prohibited by statute from approving an ANDA when certain marketing or data exclusivity protections apply to the RLD.

If the FDA in the future were to approve an NDA for SB 11285 or another small-molecule drug product candidate, such a product would be expected to be designated as an RLD. Such a designation as an RLD would

allow for a subsequent ANDA or 505(b)(2) NDA to rely in whole or in part on our RLD, as applicable. We cannot predict the interest of potential generic or follow-on competitors in the future market, whether someone will attempt to invalidate any period of 5-year or 3-year exclusivity that an approved small-molecule drug product candidate may receive or otherwise force the FDA to take other actions, or how quickly others may seek to come to market with competing products after any such marketing exclusivity period ends. In addition, should any such future generic or follow-on product be identified by the FDA as "therapeutically equivalent" to the relevant F-star small-molecule drug product candidate, if or when approved and listed in the Orange Book, physicians and pharmacists consider it to be fully substitutable for our relevant RLD. By operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient. Such competitive products may be able to immediately compete with us in each indication for which its small-molecule drug product candidates may have received approval.

The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish coverage and adequate reimbursement levels, as well as pricing policies. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford products such as our product candidates, if approved. Even if we receive approval to market one or more of our product candidates in the future, our ability to achieve acceptable levels of coverage and reimbursement for such product candidates by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize and attract additional collaboration partners to invest in the development of, our product candidates. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the EU or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage and reimbursement for drug products *exist* among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the

Medicare and Medicaid programs, play an *important* role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic/biosimilar drug or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidate and other therapies as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidate over other available and comparable products, pricing of existing drugs may limit the amount we will be able to charge for its product candidate. These payors may deny or revoke the reimbursement status of a given drug product or establish prices for new or existing marketed products at levels that are too low to enable it to realize an appropriate return on our investment in product development. If coverage and reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on products that we may develop.

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. For example, under these circumstances, physicians may limit how much or under what circumstances they will *prescribe* or administer our products and patients may deliver to purchase such products. This, in turn, could affect our ability to commercialize our products successfully and impact our profitability, results of operations, financial condition, and future success.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval.

Moreover, increasing efforts by governmental and third-party payors in the United States, the EU and other jurisdictions to *cap* or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment

for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

The future commercial success of our product candidates will depend on the degree of market acceptance of our potential therapeutic products among physicians, patients, third-party payors and the medical community.

To date, we have no products authorized for marketing and we do not expect to be able to commercialize any of our product candidates for a number of years, if ever. Even if one or more of our product candidates are approved for commercialization, they may not achieve an adequate level of acceptance by physicians, patients and the medical community, and we may not become profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of our future approved products may require significant resources and may never be successful which would prevent us from generating significant revenues or becoming profitable.

Market acceptance of our future products by physicians, patients and third-party payors will depend on a number of factors, many of which are beyond our control, including, but not limited to:

- the clinical indications for which our product candidates are approved for marketing;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or prescribing information requirements of the FDA, the EMA or other comparable foreign regulatory authorities, or any risk mitigation measures that are required to be followed as part of the product's marketing approval;
- limitations or warnings contained in the product labeling approved by the FDA, the EMA or other comparable foreign regulatory authorities, including any restrictions on concomitant use of other medications;;
- the timing of market introduction of our product candidates in relation to other potentially competitive products;
- the cost and cost-effectiveness of our product candidates in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our product candidates;
- the availability of coverage and adequate reimbursement from third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of comprehensive coverage and reimbursement by third-party payors and government authorities;
- the relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies;
- support from patient advocacy groups;
- the effectiveness of our sales and marketing efforts and distribution support; and
- the presence or perceived risk of potential product liability claims.

If our product candidates fail to gain market acceptance after receiving regulatory approval, this will have a material adverse impact on our ability to generate revenues to provide a satisfactory, or any, return on our investments. Even if some products achieve market acceptance, the market may prove not to be large enough to allow us to generate significant revenues.

Healthcare legislative reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products, (iv) restriction on coverage, reimbursement, and pricing for our products, (v) transparency reporting obligations regarding transfers of value to healthcare professionals or (vi) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect our business, financial condition and results of operations.

In March 2010, the Affordable Care Act ("ACA") was enacted, which includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers in the United States. It also included the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The ACA continues to significantly impact the United States' pharmaceutical industry. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and as a result certain sections of the law have not been fully implemented or effectively repealed. In particular, in December of 2018, a Texas U.S. District Court ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act, effective January 1, 2019. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals upheld the District Court ruling that the individual mandate was unconstitutional but remanded the case back to the lower court to determine whether other reforms enacted as part of the ACA but not specifically related to the individual mandate or health insurance, including the provisions comprising the BPCIA, could be severed from the rest of the ACA so as not to be declared invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case and allocated one hour for oral arguments, which occurred on November 10, 2020. A decision from the Supreme Court is expected to be issued in spring 2021. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted that affect healthcare expenditures. In particular, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices and the manner in which manufacturers set prices for their marketed products. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. The January 20, 2021 transition to a new Democrat-led presidential administration created new uncertainty for ongoing regulatory matters that were initiated during the Trump Administration's final year in office, including several initiatives intended to lower drug prices and reduce the out-of-pocket costs of drugs. Following his inauguration, President Biden took immediate steps to order a regulatory freeze on all pending substantive executive actions in order to permit incoming department and agency heads to review whether questions of fact, policy, and law may be implicated and to determine how to proceed.

The Further Consolidated Appropriations Act for 2020 (P.L. 116-94), signed into law in December 2019, included a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 (the "CREATES Act"). The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic and biosimilar product developers access to samples of brand products. Because generic and biosimilar product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic and biosimilar products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic or biosimilar product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic and biosimilar product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on our future commercial products are unknown.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers ("PBMs") and other members of the healthcare and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug, which could have an adverse effect on customers for our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize current or any future product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, U.S. federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Our business operations and current and future relationships with clinical investigators, healthcare professionals, consultants, third-party payors and customers may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws. If we are unable to comply, or has not fully complied, with such laws, we could face substantial penalties.

Although we do not currently have any products on the market, our current and future operations may be directly, or indirectly through our relationships with clinical investigators, healthcare professionals, customers and third-party payors, subject to broadly applicable healthcare laws U.S. federal and state fraud and abuse and other healthcare laws and regulations, including, without limitation, the Anti-Kickback Statute. Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws impact, among other things, our proposed sales, marketing and education programs and constrain our business and financial arrangements and relationships with third-party payors, healthcare professionals who participate in our clinical research program, healthcare professionals and others who recommend, purchase, or provide our approved products, and other parties through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business. Finally, our current and future operations are subject to additional healthcare-related statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business.

- the Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate **it** in order to have committed a violation. In addition, a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act, (“FCA”);

- federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- HIPAA, which created new federal criminal and civil statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by HITECH, and their implementing regulations, which impose certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security

and transmission of individually identifiable health information by covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information and require notification to affected individuals and regulatory authorities of certain breaches of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, chiropractors and, beginning in 2022 for payments and other transfers of value provided in the previous year, certain advanced non-physician healthcare practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- analogous state laws and regulations, including: state anti-kickback and false claims laws that may apply to claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral source; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products and to limit the distribution of product samples and impose requirements to ensure accountability in prescription drug sample distribution.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other laws that may apply to us, we may be subject to significant sanctions, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers

or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

The risk of us being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts or otherwise have broad coverage. For example, the definition of the "remuneration" under the Anti-Kickback Statute has been interpreted to include anything of value. Further, courts have found that if "one purpose" of remuneration is to induce referrals, the Anti-Kickback Statute is violated.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a biopharmaceutical company may run afoul of one or more of the requirements.

Obtaining and maintaining marketing approval of our current and future product candidates in one jurisdiction does not mean that we will be successful in obtaining marketing approval of our current and future therapeutic product candidates in other jurisdictions.

Obtaining and maintaining marketing approval of our current and future product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction, while a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the marketing approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable foreign regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our future products will also be subject to approval.

We may submit marketing applications in other countries in addition to the United States. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign marketing approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize our products on our own or together with suitable partners.

We do not have a sales or marketing infrastructure and have no experience in the sale or marketing of biopharmaceutical products. To achieve commercial success for any approved product, we must develop or acquire a sales and marketing organization, outsource these functions to third parties or enter into partnerships.

We may decide to establish our own sales and marketing capabilities and promote our product candidates if and when regulatory approval has been obtained in the United States and the major EU countries. There are risks

involved if we decide to establish our own sales and marketing capabilities or enter into arrangements with third parties to perform these services. Even if we establish sales and marketing capabilities, we may fail to launch our products effectively or to market our products effectively since we have no experience in the sales and marketing of biopharmaceutical products. In addition, recruiting and training a sales force is expensive and time consuming and could delay any product launch. In the event that any such launch is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to commercialize our products on our own include:

- Our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- costs of marketing and promotion above those anticipated by us.

If we enter into arrangements with third parties to perform sales and marketing services, our product revenues or the profitability of these product revenues to us could be lower than if we were to market and sell any products that we develop ourselves. Such collaborative arrangements with partners may place the commercialization of our products outside of our control and would make us subject to a number of risks including that we may not be able to control the amount or timing of resources that our collaborative partner devotes to our products or that our collaborator's willingness or ability to complete its obligations, and our obligations under our arrangements may be adversely affected by business combinations or significant changes in our collaborator's business strategy. In addition, we may not be successful in entering into arrangements with third parties to sell and market our products or may be unable to do so on terms that are favorable to us. Acceptable third parties may fail to devote the necessary resources and attention to sell and market our products effectively.

If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we may not be successful in commercializing our products, which in turn would have a material adverse effect on our business, financial condition and results of operations.

Adverse events in the field of immuno-oncology could damage public perception of our current or future therapeutic product candidates and negatively affect our business.

The commercial success of our immuno-oncology product candidates, if approved, will depend in part on public acceptance of the use of cancer immunotherapies. Adverse events in marketed products, in clinical trials of our product candidates or in clinical trials of others developing similar products and the resulting publicity, as well as any other adverse events in the field of immuno-oncology that may occur in the future, could result in a decrease in demand for any products that we may develop. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, whether related to our products or those of our competitors, our products may not be accepted by the general public or the medical community.

Future adverse events in immuno-oncology or the biopharmaceutical industry could also result in heightened governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our product candidates. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for the product candidates we develop or prevent it from receiving marketing approval at all.

The market opportunities for any current or future immuno-oncology product candidates we develops, if approved, may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small.

Cancer therapies are sometimes characterized as first-line, second-line or third-line, and the FDA often approves new therapies initially only for third-line use. When cancer is detected early enough, first-line therapy, usually chemotherapy, hormone therapy, surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. We expect to initially seek approval of our current and future immuno-oncology product candidates as a therapy for patients who have received one or more prior treatments. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval potentially as a first-line therapy, but there is no guarantee that product candidates we develop, even if approved, would be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

In addition, subsequent developments in cancer biomarkers may demonstrate that our product candidates are not suitable for the treatment of certain cancers or subpopulations, thereby reducing the market opportunity for those product candidates. Even if we obtain significant market share for any product candidate, if approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications, including to be used as first- or second-line therapy or for other related cancer indications.

If the market opportunities for our product candidates are smaller than we believe they are, even assuming approval of a product candidate, our business may suffer.

Our projections of both the number of people who are affected by disease within our potential target indications, as well as the subset of these people who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, healthcare utilization databases and market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Likewise, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our business, financial condition and results of operations.

A pandemic, epidemic, or outbreak of an infectious disease, such as COVID-19, may materially and adversely affect our business and financial results and could cause a disruption to the development of our product candidates.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. Recently, COVID-19 has spread across the United States and in other countries, including specifically the U.K., where our primary office and laboratory space is located. The coronavirus pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. The extent to which the novel coronavirus impacts our operations or those of our third-party collaborators and partners, including our preclinical studies or clinical trial operations, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that will emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. The continued spread of COVID-19 or variants thereof globally could adversely impact our preclinical or clinical trial operations, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. For example, similar to other biopharmaceutical companies, we may experience delays in initiating preclinical studies, enrolling our clinical trials, or dosing of

patients in our clinical trials as well as in activating new trial sites. COVID-19 may also affect employees of third-party CROs located in affected geographies that we rely upon to carry out clinical trials. Any negative impact COVID-19 has to patient enrollment or treatment or the execution of our product candidates could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results. Also, there is a risk of corporate and other tax increases or decreases to current tax credits or reliefs as a result of government expenditures to address COVID-19, which could have a material adverse effect on our future financial results.

Additionally, timely enrollment in planned clinical trials is dependent upon clinical trial sites that could be adversely affected by global health matters, such as pandemics. We plan to conduct clinical trials for our mAb^2 product candidates in geographies that are currently being affected by the COVID-19. Some factors from the novel coronavirus outbreak that will delay or otherwise adversely affect enrollment in the clinical trials of our mAb^2 product candidates, as well as our business generally, include:

- the potential diversion of healthcare resources away from the conduct of clinical trials to focus on pandemic concerns, including the attention of physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our prospective clinical trials;
- limitations on travel that could interrupt key trial and business activities, such as clinical trial site initiations and monitoring, domestic and international travel by employees, contractors or patients to clinical trial sites, including any government-imposed travel restrictions or quarantines that will impact the ability or willingness of patients, employees or contractors to travel to our clinical trial sites or secure visas or entry permissions, a loss of face-to-face meetings and other interactions with potential partners, any of which could delay or adversely impact the conduct or progress of our prospective clinical trials;
- the potential negative affect on the operations of our third-party manufacturers;
- interruption in global shipping affecting the transport of clinical trial materials, such as patient samples, investigational drug product and conditioning drugs and other supplies used in our prospective clinical trials; and
- business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments.

Risks Related to our Intellectual Property

We rely on patents and other intellectual property rights to protect our product candidates and our modular antibody technology platform, the enforcement, defense and maintenance of which may be challenging and costly. Failure to protect or enforce these rights adequately could harm our ability to compete and impair our business.

Our commercial success depends in part on obtaining and maintaining patents and other forms of intellectual property rights for our product candidates, methods used to manufacture those product candidates and/or methods for treating patients using those product candidates, or on in-licensing such rights. Failure to protect or to obtain, maintain or extend adequate patent and other intellectual property rights could materially adversely affect our ability to develop and market our products and product candidates.

Patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology at issue. We cannot be certain that patents will be issued or granted with respect to applications that are currently pending, or that issued or granted patents will not later be found to be invalid or enforceable. The patent position of biopharmaceutical companies is generally uncertain because it involves

complex legal and factual considerations that have in recent years been the subject of much litigation. The standards applied by the European Patent Office ("EPO"), the U.S. Patent and Trademark Office ("USPTO"), and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biopharmaceutical patents. Consequently, patents may not issue from our pending patent applications. As such, we do not know the degree of future protection that we will obtain that relates to our proprietary product candidates and modular antibody technology platform. The scope of patent protection that the EPO and the USPTO will grant with respect to the bispecific antibodies in our product pipeline is uncertain. It is possible that the EPO and the USPTO will not allow broad antibody claims that cover antibodies closely related to our mAb^2 product candidates as well as the specific antibody. As a result, upon receipt of EMA or FDA approval, competitors may be free to market antibodies almost identical to our, including biosimilar antibodies, thereby decreasing our market share. However, a competitor cannot submit to the FDA an application for a biosimilar product based on one of our products until four years following the date of approval of our "reference product," and the FDA may not approve such a biosimilar product until 12 years from the date on which the reference product was approved, with a potential six-month extension of exclusivity if certain pediatric studies are conducted and the results are reported to the FDA.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or collaboration partners may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors, licensees or collaboration partners will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Further, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaboration partners' patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our modular antibody technology platform or our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Our competitors may be able to circumvent our patents by developing similar or alternative product candidates in a non-infringing manner. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, relating to technology that we license from or license to third parties and are reliant on our licensors, licensees or collaboration partners. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaboration partners fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current or future licensors, licensees or collaboration partners are not fully cooperative or disagree with it as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. The patent examination process may require us or our current or future licensors, licensees or collaboration partners to narrow the scope of the claims of our or our licensors', licensees' or collaboration partners' pending and future patent applications, which may limit the scope of patent protection that may be obtained.

We cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application. Furthermore, if third parties have filed such patent applications on or before March 15, 2013, an interference proceeding can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such applications after March 15, 2013, a derivation proceeding can be initiated by such third parties to determine whether our invention was derived from theirs. Even where we have a valid and enforceable patent,

we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license.

We have pending patent applications at the USPTO, the EPO, and the patent offices of other foreign jurisdictions, and it is possible that we will need to defend other patents from challenges by others from time to time. Certain of our U.S. patent applications have been and may in the future be the subject of submissions of prior art by third parties. Even if patents do successfully issue, third parties may initiate an opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation action in court or before patent offices, or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed, invalidated, or held unenforceable, in whole or in part. For example, opposition proceedings at the EPO are increasingly common, and are costly and time consuming to defend. Similar proceedings are available in other patent offices around the world. It is possible that one or more of our U.S. patents may be challenged by parties who file a request for post-grant review or *inter partes* review or *ex parte* reexamination. Post-grant proceedings are increasingly common in the United States and are costly to defend. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, or allow third parties to commercialize our product candidates and compete directly with us, without payment to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with it to license, develop or commercialize current or future product candidates. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful, and issued patents relating to one or more of our product candidates or our modular antibody technology platform could be found invalid or unenforceable if challenged in court.

To protect our competitive position, we may from time to time need to resort to litigation in order to enforce or defend any patents or other intellectual property rights owned by or licensed to us, or to determine or challenge the scope or validity of patents or other intellectual property rights of third parties. As enforcement of intellectual property rights is difficult, unpredictable and expensive, many of our or our collaboration partners' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our collaboration partners can. Accordingly, despite our or our collaboration partners' efforts, we or our collaboration partners may not prevent third parties from infringing upon or misappropriating intellectual property rights we own or control, particularly in countries where the laws may not protect those rights as fully as in the United States and in Europe. We may fail in enforcing our rights, in which case our competitors may be permitted to use our technology without being required to pay it any license fees. In addition, however, litigation involving our patents carries the risk that one or more of our patents will be held invalid (in whole or in part, on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize our product candidates or use our modular antibody technology platform, and then compete directly with us, without payment to us.

If we were to initiate legal proceedings against a third party to enforce a patent relating to one of our products, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States or in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. A claim for a validity challenge may be based on failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. A claim for unenforceability assertion could be an allegation that someone connected with prosecuting the patent withheld relevant information from the USPTO or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during

prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our product candidates or certain aspects of our modular antibody technology platform. Such a loss of patent protection could have a material adverse impact on our business. Interference or derivation proceedings provoked by third parties or brought by it or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to us from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Further, litigation could result in substantial costs and diversion of management resources, regardless of the outcome, and this could harm our business and financial results. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Intellectual property rights of third parties could adversely affect our ability to commercialize our product candidates, such that we could be required to litigate or obtain licenses from third parties in order to develop or market our product candidates. Such litigation is, and will continue to be, costly and any required licenses may not be available on commercially reasonable terms.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts. Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation proceedings, oppositions and *inter partes* reexamination proceedings before the USPTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that we may be subject to claims of infringement of the patent rights of third parties.

Our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover our products or product candidates or elements thereof, our manufacture or uses relevant to our development plans, the targets of our mAb^2 product candidates, or other attributes of our mAb^2 product candidates or our mAb ^{2} technology. In such cases, We may not be in a position to develop or commercialize products or product candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms or at all.

It is also possible that we fail to identify relevant patents or patent applications. For example, certain U.S. applications filed after November 29, 2000 that will not be filed outside the United States may remain confidential until issuance of a patent. In general, patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications relating to our products or platform technology could have been filed by others without our knowledge. Furthermore, we operate in a highly competitive field, and given our limited resources, it is unreasonable to monitor all patent applications purporting to gain broad coverage in the areas in which we are active. Additionally, pending patent applications which have

been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our products or the use of our products.

Parties making claims of infringement against us or defending against our invalidity actions may be able to sustain the costs of complex patent litigation more effectively than us can because they have substantially greater resources. If we fail in any such dispute, in addition to being forced to pay damages, we or our licensees may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates so that we no longer infringe the third-party intellectual property rights. We may be required to seek a license to any such technology that we are found to infringe, which license may not be available on commercially reasonable terms, or at all. Even if we or our collaboration partners obtain a license, it may be non-exclusive; thereby giving our competitors access to the same technologies licensed to us or our licensors or collaboration partners. Moreover, such a license may require us to pay royalties to the licensor; thus, reducing our expected revenues. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent in the United States. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, we could have a substantial adverse effect on our share price. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

In addition, if the breadth or strength of protection provided by our or our collaboration partners' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.

We are a party to license agreements, and we may in the future need to obtain additional licenses from others to advance our research and development activities or allow the commercialization of our product candidates. Our current license agreements impose, and we expect that future license agreements will impose, various development, diligence, commercialization and other obligations on us. In spite of our efforts, our current or future licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize product candidates and otherwise use technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to our and we may be required to cease our development and commercialization of our product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;

- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected mAb^2 product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

Because our programs may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire or in-license such proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to our size, cash resources and greater clinical development and commercialization capabilities.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain a license to third-party intellectual property rights necessary for the development of a product candidate or program, we may have to abandon development of that product candidate or program, and our business and financial condition could suffer.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. If other entities use trademarks similar to our in different jurisdictions, or have senior rights to our, it could interfere with our use of our current trademarks throughout the world.

If we do not obtain protection under the Hatch-Waxman Amendments and similar non-U.S. legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.

Patents have a limited duration. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates, their manufacture or use are obtained, once the patent life has expired, we may be open to competition from competitive medications, including biosimilar medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and in-licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments to the FDCA, and similar legislation in the EU. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. The patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug may be extended. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension, as well as the scope of the protection during such an extension, could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner than we expect. As a result, our revenue from applicable products could be reduced, possibly materially.

We enjoy only limited geographical protection with respect to certain patents and may face difficulties in certain jurisdictions, which may diminish the value of intellectual property rights in those jurisdictions.

We often file our first patent application (i.e., priority filing) in Great Britain or with the USPTO. International applications under the Patent Cooperation Treaty (“PCT”), are usually filed within 12 months after the priority filing. Based on the PCT filing, national and regional patent applications may be filed in additional jurisdictions where we believe our product candidates may be marketed. We have so far not filed for patent protection in all national and regional jurisdictions where such protection may be available. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national/regional patent is an independent proceeding which may lead to situations in which applications might be refused by certain patent offices, while granted by others, and the scope of patent protection may vary for the same product candidate or technology.

Competitors may use our and our collaboration partners’ technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors or collaboration partners have patent protection, but enforcement is not as strong as that in the United States and the Europe. These products may compete with our product candidates, and our and our collaboration partners’ patents or other intellectual property rights may not be effective or sufficient to prevent them from competing with us.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States and the Europe, and companies have encountered significant difficulties in protecting and

defending such rights in such jurisdictions. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

Some countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business and results of operations may be adversely affected.

Proceedings to enforce our and our collaboration partners' patent rights in foreign jurisdictions could result in substantial costs and divert our and our collaboration partners' efforts and attention from other aspects of our business, could put our and our collaboration partners' patents at risk of being invalidated or interpreted narrowly and our and our collaboration partners' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors or collaboration partners. We or our collaboration partners may not prevail in any lawsuits that we or our licensors or collaboration partners initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- the patents of third parties may have an adverse effect on our business;
- we or any current or future licensors or strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or any future licensors or strategic partners might not have been the first to file patent applications relating to certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using our products or technologies could use the intellectual property of others without obtaining a proper license; and
- we may not develop additional technologies that are patentable.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological complexity and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, the America Invents Act (the "AIA"), has been enacted in the United States, resulting in significant changes to the U.S. patent system.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before we do could therefore be awarded a patent relating to an invention of ours even if we had made the invention before it was made by the third party. This requires us to be cognizant of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO via various proceedings including, e.g., post-grant review, *inter partes* review, and derivation proceedings. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Additionally, the U.S. Supreme Court and the Court of Appeals for the Federal Circuit have ruled on patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and protect other proprietary information.

We consider proprietary trade secrets, confidential know-how and unpatented know-how to be important to our business. We may rely on trade secrets or confidential know-how to protect our technology, especially where patent protection is believed to be of limited value. However, trade secrets and confidential know-how are difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements and invention assignment agreements with us. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Current or former employees,

consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party obtained illegally and is using trade secrets or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. Furthermore, if a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

Failure to obtain or maintain trade secrets or confidential know-how trade protection could adversely affect our competitive position. Moreover, our competitors may independently develop substantially equivalent proprietary information and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets or confidential know-how.

Under certain circumstances, we may also decide to publish some know-how to attempt to prevent others from obtaining patent rights relating to such know-how.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for F-star, we may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and F-star could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO, the EPO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO, the EPO and various foreign governmental patent agencies require compliance with a number of procedural, documentaries, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents.

If we or our licensors or collaboration partners fail to maintain the patents and patent applications relating to our product candidates, our competitors might be able to enter the market, which would have an adverse effect on our business.

Risks Related to our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators, contracted laboratories and CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators, contracted laboratories and third-party CROs, to conduct our preclinical studies and clinical trials in accordance with applicable regulatory requirements and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and controls only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with good laboratory practices ("GLPs"), as applicable, and good clinical practice ("GCP") requirements, which are regulations and guidelines enforced by the FDA, the EMA and other comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GLPs and GCPs through periodic inspections of laboratories conducting GLP studies, and clinical trial sponsors, principal investigators, CROs, and trial sites when auditing for GCP compliance. If we, our investigators or any of our CROs or contracted laboratories fail to comply with applicable GLPs and GCPs, as applicable, the data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, the EMA or other comparable foreign regulatory authorities may require us to perform additional preclinical studies or clinical trials before approving our marketing applications for our therapeutic product candidates. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our preclinical studies or clinical trials comply with applicable GLP or GCP regulations. In addition, our clinical trials must be conducted with product produced in compliance with applicable cGMP regulations. Our failure to comply with these regulations may require us to repeat preclinical studies or clinical trials, which would delay the regulatory approval process.

Further, these laboratories, investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent laboratories, investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

There is a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. If any of our relationships with these third-party laboratories, CROs or clinical investigators terminate, we may not be able to enter into arrangements with alternative laboratories, CROs or investigators or to do so in a timely manner or on commercially reasonable terms. If laboratories, CROs or clinical investigators do not successfully carry out their contractual duties or obligations or meet expected

deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our preclinical or clinical protocols, regulatory requirements or for other reasons, our preclinical studies or clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional laboratories or CROs (or investigators) involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new laboratory or CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manages our relationships with our contracted laboratories and CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and results of operations.

In addition, clinical investigators may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the preclinical study or clinical trial, the integrity of the data generated at the applicable preclinical study or clinical trial site may be questioned and the utility of the preclinical study or clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing our clinical-stage product candidate or any future therapeutic product candidates it may develop.

The manufacture of biotechnology products is complex, and manufacturers often encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, or otherwise fail to comply with their contractual obligations, the development or commercialization of our product candidates could be delayed or stopped.

The manufacture of biotechnology products is generally complex and requires significant expertise and capital investment. We and our contract manufacturers must comply with cGMP regulations and guidelines for clinical trial product manufacture and for commercial product manufacture. Manufacturers of biotechnology products often encounter difficulties in production, particularly in scaling up, addressing product quality, product comparability, validating production processes and mitigating potential sources of contamination. These problems include difficulties with raw material procurement, production costs and yields, quality control, product quality, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if microbial, viral or other contaminations are discovered in therapeutic products or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

We cannot assure you that manufacturing problems, including supply chain disruptions of any of mAb ^{2} product candidates or other products will not occur in the future. Any delay or interruption in the supply of preclinical or clinical trial supplies, including any delays arising from circumstances related to the COVID-19 pandemic, could delay the completion of these trials, increase the costs associated with maintaining these trial programs and, depending upon the period of delay, require us to commence new trials at additional expense or terminate trials completely.

We rely on third parties to supply and manufacture our product candidates, and we expect to continue to rely on third parties to manufacture our products, if approved. The development of such product candidates and the commercialization of any products, if approved, could be stopped, delayed or made less profitable if any such third party fails to provide us with sufficient quantities of product candidates or products or fails to do so at acceptable quality levels or prices or fails to maintain or achieve satisfactory regulatory compliance.

We do not currently have the infrastructure or capability internally to manufacture our product candidates for use in the conduct of our preclinical studies and clinical trials or for commercial supply if our products are approved. We rely on, and expect to continue to rely on, contract manufacturing organizations ("CMOs"). We currently rely mainly on a few CMOs for the manufacturing of our product candidates. Any replacement of our CMOs could require significant effort and expertise because there may be a limited number of qualified CMOs. Reliance on third-party providers may expose us to more risk than if we were to manufacture our product candidates ourselves. We are dependent on our CMOs for the production of our product candidates in accordance with relevant regulations, such as cGMP, which includes, among other things, quality control, quality assurance and the maintenance of records and documentation. Moreover, many of the third parties with whom we contracts may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting product development activities that could harm our competitive position.

If we were to experience an unexpected loss of supply of or if any supplier were unable to meet our demand for any of our product candidates, we could experience delays in our research or planned clinical trials or future commercialization activities. We could be unable to find alternative suppliers of acceptable quality, in the appropriate volumes and at an acceptable cost. Moreover, our suppliers are often subject to strict manufacturing requirements and rigorous testing requirements, which could limit or delay production. The long transition periods needed to switch manufacturers and suppliers, if necessary, could significantly delay our clinical studies and the commercialization of our products, if approved, which could materially adversely affect our business, financial condition and results of operation.

In complying with the applicable manufacturing regulations of the FDA, the EMA and other comparable foreign regulatory authorities, we and our third-party suppliers must spend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. The failure to comply with these requirements could result in an enforcement action against us, including the seizure of products and shutting down of production. We and any of these third-party suppliers may also be subject to audits by the FDA, the EMA or other comparable foreign regulatory authorities. If any of our third-party suppliers fails to comply with cGMP or other applicable manufacturing regulations, our ability to develop and commercialize our future therapeutics products could suffer significant interruptions. We face risks inherent in relying on a single CMO, as any disruption, such as a fire, natural hazards, disease outbreaks including but not limited to the ongoing COVID-19 pandemic, or vandalism at the CMO could significantly interrupt our manufacturing capability. All of our CMOs currently do not have alternative production plans in place or disaster-recovery facilities available. In case of a disruption, we will have to establish alternative manufacturing sources. This would require substantial capital on our part, which we may not be able to obtain on commercially acceptable terms or at all. Additionally, we would likely experience months of manufacturing delays as the CMO builds or locates replacement facilities and seeks and obtains necessary regulatory approvals. If this occurs, we will be unable to satisfy manufacturing needs on a timely basis, if at all.

The manufacturing of all of our mAb ^{2} product candidates requires using cells that are stored in a cell bank. We have one master cell bank for each product manufactured in accordance with cGMP. Working cell banks have not yet been manufactured. Half of each master cell bank is stored at a separate site so that in case of a catastrophic event at one site we believe sufficient vials of the master cell banks are left at the alternative storage site to continue manufacturing. We believe sufficient working cell banks could be produced from the vials of the master cell bank stored at a given site to assure product supply for the future. However, it is possible that we could lose multiple cell banks and have our manufacturing significantly impacted by the need to replace these cell banks, which could materially adversely affect our business, financial condition and results of operations.

We rely and expect to continue to rely on collaborative partners regarding the development of certain of our research programs and product candidates. If we are not able to maintain our current relationships or enter into new strategic relationships, our business, financial condition, commercialization prospects and results of operations may be adversely affected.

We are, and expect to continue to be, dependent on partnerships with partners relating to the development and commercialization of certain of our existing and future research programs and product candidates. We currently have collaborative research relationships with each of Ares Trading S.A. ("Ares"), an affiliate of Merck KGaA, Darmstadt, Germany, Denali Therapeutics Inc. and Kymab Limited for the development of certain mAb^2 product candidates resulting from such collaborations. In addition, we have a clinical collaboration agreement with Roche on the use of the PD-L1 checkpoint inhibitor atezolizumab (Tecentriq) in combination cohorts of the SB 11285 trial. We have, and may in the future, depending on our business strategy, continue to have discussions on potential partnering opportunities with various pharmaceutical companies. If we fail to enter into or maintain collaborations on reasonable terms or at all, our ability to develop our existing or future research programs and product candidates could be delayed, the commercial potential of our product could change, and our costs of development and commercialization could increase. Furthermore, we may find that our programs require the use of intellectual property rights held by third parties, and the growth of our business may depend in part on our ability to acquire or in-license these intellectual property rights.

Our dependence on collaborative partners subjects us to a number of risks, including, but not limited to, the following:

- we may not be able to control the amount and timing of resources that the collaboration partner devotes to our research programs and product candidates;
- for collaboration agreements where we are solely or partially responsible for funding development expenses through a defined milestone event, the payments we receive from the collaboration partner may not be sufficient to cover the expenses we have or would need to incur in order to achieve that milestone event;
- we may be required to relinquish significant rights to our collaborative partners, including rights to exploit our intellectual property and marketing and distribution rights;
- if the development of the relevant product candidates is not successful, our anticipated payments under any partnership agreement (e.g., royalty payments for licensed products) may not materialize;
- we rely on the information and data received from third parties regarding their research programs and product candidates and will not have control of the process conducted by the third party in gathering and composing such data and information;
- if rights to develop and commercialize our product candidates that are subject to collaborations revert to us for any reason, we may not have sufficient financial resources to develop such product candidates, which may result in us failing to recognize any value from our investments in developing such product candidates;
- a collaborative partner may develop a competing product either by itself or in collaboration with others, including one or more of our competitors, or seek to restrict us from working with other collaborators that may compete with our partner's products, which could deprioritize the development of our products;
- our collaborative partners' willingness or ability to complete their obligations under our partnership arrangements may be adversely affected by business combinations or significant changes in a collaborative partner's business strategy;
- we may experience delays in, or increases in the costs of, the development of our research programs and mAb ^{2} product candidates due to the termination or expiration of collaborative research and development arrangements;

- we may have disagreements with collaborative partners, including disagreements over proprietary rights, contract interpretation, non-competition limitations, or the preferred course of development, that might cause delays or termination of the research, development or commercialization of our product candidates, might lead to additional responsibilities for us with respect to our product candidates, or might result in litigation or arbitration, any of which may be time-consuming and expensive;
- collaborative partners may not properly maintain or defend our intellectual property rights or may use proprietary information in such a way as to invite litigation or other intellectual property-related proceedings that could invalidate our intellectual property or jeopardize our proprietary information or expose us to potential litigation; or
- collaborative partners may infringe or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability.

We face significant competition in seeking appropriate collaborative partners. Our ability to reach a definitive agreement for a partnership will depend, among other things, upon an assessment of the collaborator's resources and expertise, the terms and conditions of the proposed partnership and the proposed collaborator's evaluation of a number of factors. These factors may include the design or results of preclinical studies or clinical trials, the likelihood of regulatory approval, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such mAb^2 product candidate to patients, the potential of competing products, the existence of any uncertainty with respect to our ownership of technology (which can exist if there is a challenge to such ownership regardless of the merits of the challenge) and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a partnership could be more attractive than the one with us.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization, reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop mAb^2 product candidates or bring them to market and generate product revenue.

Risks Related to our Business Operations, Employee Matters and Managing Growth

Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.

Our success depends upon the continued contributions of our key management, scientific and technical personnel, many of whom have been instrumental for us and have substantial experience with our mAb^2 product candidates, mAb2 technology and modular antibody technology platform. We are highly dependent upon our senior management, particularly Eliot Forster, our Chief Executive Officer, Neil Brewis, our Chief Scientific Officer, and Louis Kayitalire, our Chief Medical Officer, as well as our senior scientists and other members of our senior management team.

The loss of key managers and senior scientists could delay our research and development activities. In addition, our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified management, scientific and medical personnel. Many other biotechnology and pharmaceutical companies and academic institutions that we compete with for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry

than we do. Therefore, we might not be able to attract or retain these key persons on conditions that are economically acceptable. Furthermore, we will need to recruit new managers and qualified scientific personnel to develop our business if we expand into fields that will require additional skills. Our inability to attract and retain these key persons could prevent us from achieving our objectives and implementing our business strategy, which could have a material adverse effect on our business and prospects.

We expect to expand our development, regulatory and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our business is subject to economic, political, regulatory and other risks associated with international operations.

As a company incorporated and based in the United Kingdom, our business is subject to risks associated with conducting business internationally. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- differing regulatory requirements for product approvals;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates of the pound sterling, U.S. dollar, euro and currency controls;
- changes in a specific country's or region's political or economic environment, including the implications of the United Kingdom's withdrawal from the European Union and entrance into the Trade and Cooperation Agreement between the United Kingdom and the European Union, which remains subject to the European Union's procedures;
- trade protection measures, import or export licensing requirements or other restrictive actions by governments;
- differing reimbursement regimes and price controls in certain international markets;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad, including, for example, the variable tax treatment in different jurisdictions of share options granted under our employee stock plan or equity incentive plan;

- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Exchange rate fluctuations may materially affect our results of operations and financial condition.

Due to the international scope of our operations, our assets, earnings and cash flows are affected by fluctuations in the exchange rates of several currencies, particularly the U.S. dollar and pound sterling. The functional currency of our English subsidiaries is the pound sterling, and the majority of our operating expenses are paid in pounds sterling. The functional currency of our Austrian subsidiary is the euro.

Additionally, although we are based primarily in the United Kingdom, we may receive payments from our business partners in U.S. dollars, Swiss francs and euros and we regularly acquire services, consumables and materials in U.S. dollars and euros. Further, potential future revenue may be derived from the United States, countries within the euro zone and various other countries around the world. These future revenues may also be affected by fluctuations in foreign exchange rates which may, in turn, have a significant impact on our results of operations and cash flows from period to period. As a result, to the extent we continue our expansion on a global basis, we expect that increasing portions of our revenue, cost of revenue, assets and liabilities will be affected by fluctuations in currency valuations. We may, therefore, experience economic loss and a negative impact on earnings or net assets solely as a result of currency exchange rate fluctuations.

Our business and operations would suffer in the event of computer system failures, cyber-attacks or a deficiency in our, or our collaborators' or third-party vendors', cyber-security.

We collect, store and transmit large amounts of confidential information, including personal information, operational and financial transactions and records, clinical trial data and information relating to intellectual property, on internal information systems and through the information systems of collaborators and third-party vendors with whom we contract. Despite the implementation of security measures, these information systems are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the internet or other mechanisms, attachments to emails, persons inside our organization, or persons with access to systems inside the organization. No such security measures can eliminate the possibility of the information systems' improper functioning or the improper access or disclosure of confidential or personally identifiable information such as in the event of cyber-attacks. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, criminals, ex-U.S. governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased.

Additionally, outside parties may attempt to fraudulently induce employees, collaborators, or other third-party vendors to disclose sensitive information or take other actions, including making fraudulent payments or downloading malware, by using "spoofing" and "phishing" emails or other types of attacks. We have previously experienced, and in the future may experience "Phishing" attacks despite efforts to prevent and mitigate future instances. For example, in recent years we were the target of cyber-attacks comprised of phishing incidents where an immaterial unauthorized payment was made based on misrepresentations or confidential company information was inadvertently shared with an unauthorized external party. The related immaterial payment was recovered by us upon identification of the incident. The unauthorized data shared was anonymized therefore no GDPR protection regulations were breached. After an internal investigation, it was determined that no further

action was required under either U.K., U.S. federal or state law. It was deemed that the cyber-attacks did not have a material impact to our business or financial condition. As a result of these incidents we, increased our cybersecurity training for all staff. While we believe we responded appropriately, including implementing remedial measures to stop this cyber-attack and with the goal of preventing similar events in the future, there can be no assurance that we will be successful in these remedial and preventative measures or successfully mitigating the effects of future cyber-attacks.

If such future events were to occur and cause interruptions in our operations, it could result in a material disruption of our clinical and research and development activities and business operations. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information or making of fraudulent payments, we could incur material legal claims and liability, damage to our reputation, suffer loss or harm to our intellectual property rights, face significant financial exposure, including incurring significant costs to remediate possible injury to the affected parties and the further research, development and commercial efforts of our future mAb^{2}products and product candidates could be delayed.

Our employees, independent contractors, vendors, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, independent contractors, vendors, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA, the EMA and other comparable foreign regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation.

We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending itself or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business, financial condition and results of operations.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions, including civil or criminal penalties, private litigation, and adverse publicity and could negatively affect our operating results and business.

We and any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations, such as laws and regulations that address privacy and data security. In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, including Section 5 of the Federal Trade Commission Act, that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data that are subject to privacy and security requirements under HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

We are subject to the U.K. Bribery Act 2010, the U.S. Foreign Corrupt Practices Act of 1977, and other anti-corruption laws, as well as export control laws, import and customs laws, trade and economic sanctions laws and other laws governing our operations.

Our operations are subject to anti-corruption laws, including the U.K. Bribery Act 2010 (the "Bribery Act"), the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act and other anti-corruption laws that apply in countries where we do business. The Bribery Act, the FCPA and these other laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, a financial or other advantage to government officials or other persons to induce them to improperly perform a relevant function or activity (or reward them for such behavior).

Under the Bribery Act, we may also be liable for failing to prevent a person associated with us from committing a bribery offense. We, along with those acting on our behalf and our commercial partners, operate in a number of jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we participate in collaborations and relationships with third parties whose corrupt or illegal activities could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws, even if we do not explicitly authorize or have actual knowledge of such activities. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

Compliance with the Bribery Act, the FCPA and these other laws is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, anti-corruption laws present particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials for purposes of the FCPA.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European

Union, including applicable export control regulations, economic sanctions and embargoes on certain countries and persons, anti-money laundering laws, import and customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses. Such liabilities could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws could also have an adverse impact on our reputation, business, results of operations and financial condition. Further, the failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

Legal, political and economic uncertainty surrounding the exit of the United Kingdom from the European Union may be a source of instability in international markets, create significant currency fluctuations, adversely affect our operations in the United Kingdom and pose additional risks to our business, revenue, financial condition, and results of operations.

On June 23, 2016, the electorate in the United Kingdom voted in favor of Brexit. Thereafter, on March 29, 2017, the country formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The withdrawal of the United Kingdom from the European Union took effect on January 31, 2020, with a transition period that ended on December 31, 2020. The United Kingdom entered into a trade agreement known as the Trade and Cooperation Agreement, which is provisionally applicable as of January 1, 2021 but has not yet been ratified by the European Parliament. We are currently evaluating the potential impacts on our business of the new Trade and Cooperation Agreement. The implementation of the Trade and Cooperation Agreement, and development relating to matters not covered by the Agreement, could lead to a period of considerable uncertainty and volatility, particularly in relation to United Kingdom financial and banking markets. Weakening of economic conditions or economic uncertainties could harm our business, and if such conditions emerge in the United Kingdom or in the rest of Europe, it may have a material adverse effect on our operations.

Currency exchange rates in the pound sterling and the euro with respect to each other and the U.S. dollar have already been adversely affected by Brexit and that may continue to be the case. In addition, the United Kingdom

no longer benefits from international trade agreements negotiated by the European Union on behalf of its members, which may result in increased trade barriers which could make doing business in Europe and elsewhere more difficult. The United Kingdom has begun to enter into its own international trade agreements, and the economic impacts of those new agreements are not yet known.

We may also face new and additional regulatory costs and challenges from Brexit that could have a material adverse effect on operations. Since a significant proportion of the regulatory framework in the United Kingdom is derived from EU directives and regulations, changes resulting from Brexit could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the European Union. Following its departure from the European Union and the expiration of the transitional period, the United Kingdom recently adopted a decentralized and mutual recognition reliance procedure for marketing authorizations that allows the United Kingdom's clinical trial regulator, the MHRA, to consider marketing authorizations granted in the European Union or the three additional European Economic Area countries. However, additional requests for information may arise and additional time may be required with respect to applications for marketing authorizations in the United Kingdom using these procedures. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing product candidates in the United Kingdom and/or the EU and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or EU for our product candidates, which could significantly and materially harm our business.

Item 1B. Unresolved Staff Comments.

Not applicable

Item 2. Properties.

Our principal operations are based in Cambridge, United Kingdom and house our office, research and development and laboratory facility space pursuant to a lease agreement that expires in 2024. A description of the primarily facilities we lease as of December 31, 2020 is included in the table below.

Leased Facilities		Square ft
Eddeva B920, Babraham Research Campus, Cambridge, UK	Corporate Headquarters	12,073
Building 730, Babraham Research Campus, Cambridge, UK	Lab Space	810

In addition, we have a virtual office agreement with Regus Management Group, LLC in Cambridge Massachusetts. We also have two additional locations in Hopkinton, Massachusetts, which we are leased to subtenants. We believe that existing facilities are adequate to meet our current and foreseeable requirements.

Item 3. Legal Proceedings.

On September 3, 2020, a Spring Bank stockholder filed a complaint in the United States District Court for the Southern District of New York (Lenthall v. Spring Bank Pharmaceuticals, Inc. et al, Case No. 1:20-cv-07219 (S.D.N.Y.)), against Spring Bank and the members of Spring Bank's Board of Directors (the "individual defendants"), alleging violations of Section 14(a) of the Exchange Act and Rule 14a-9 promulgated thereunder, and as against the individual defendants, alleging violations of Section 20(a) of the Exchange Act and of Delaware state law. The plaintiff alleges that the defendants made materially misleading disclosures in Spring Bank's Form S-4 registration statement filed in connection with the Exchange (the "Form S-4"), by allegedly omitting material information with respect to (i) financial projections relating to Spring Bank and F-star Ltd, (ii) Ladenburg's fairness opinion and any financial analyses conducted on Spring Bank. The plaintiff in Lenthall sought declaratory and injunctive relief to enjoin the Exchange as well as damages and attorneys' and experts' fees. While the Company believes there is no merit to this complaint, in March 2021, the Company executed a settlement agreement relating to this matter for an amount that is immaterial to the financial statements.

On September 8, 2020, in the United States District Court for the District of Delaware, a purported class action (Adam Franchi v. Spring Bank Pharmaceuticals, Inc. et al, Case No. 1:20-cv-01198 (D. Del.)) was filed against Spring Bank, members of Spring Bank's Board of Directors and F-star Ltd, alleging violations of Section 14(a) of the Exchange Act and Rule 14a-9 promulgated thereunder, and as against the individual defendants, alleging violations of Section 20(a) of the Exchange Act. This complaint alleged that the defendants made materially misleading disclosures in the Form S-4 by allegedly omitting material information with respect to (i) financial projections relating to Spring Bank and F-star Ltd, (ii) the confidentiality agreements entered into by Spring Bank prior to its engagement of Ladenburg, (iii) the process leading up to the execution of the Exchange Agreement and (iv) any financial analyses performed by Ladenburg. The plaintiff in Franchi sought declaratory and injunctive relief to enjoin the Exchange; or in the event of consummation of the Exchange, rescissory damages against the defendants; filing by the defendants of a Registration Statement deemed not to be materially misleading by the plaintiff; and attorneys' and experts' fees. While the Company believes there is no merit to this complaint, in March 2021, the Company executed a settlement agreement relating to this matter for an amount that is immaterial to the financial statements.

On September 18, 2020, in the United States District Court for the Southern District of New York, another Spring Bank stockholder filed a complaint (Arshad v. Spring Bank Pharmaceuticals, Inc., et al., Case No. 1:20-cv-07723 (S.D.N.Y.)), against Spring Bank and the members of Spring Bank's Board of Directors, alleging violations of Section 14(a) of the Exchange Act and Rule 14a-9 promulgated thereunder, and as against the individual defendants, alleging violations of Section 20(a) of the Exchange Act. The plaintiff alleged that the defendants made materially misleading disclosures in the Form S-4 by allegedly omitting material information with respect to (i) financial projections relating to Spring Bank and F-star Ltd, (ii) Ladenburg's fairness opinion and (iii) the process relating to the Exchange. The plaintiff in Arshad sought declaratory and injunctive relief to enjoin the Exchange; or in the event of consummation of the Exchange, rescissory damages against the defendants; filing by the defendants of a Registration Statement deemed not to be materially misleading by the plaintiff; and attorneys' and experts' fees. While the Company believes there is no merit to this complaint, in March 2021, the Company executed a settlement agreement relating to this matter for an amount that is immaterial to the financial statements.

On October 29, 2020, in the United States District Court Eastern District of New York, another Spring Bank stockholder filed a complaint (Nowakowski v. Spring Bank Pharmaceuticals, Inc., et al., Case No. 1:20-cv-05219 (E.D.N.Y.)), against Spring Bank and the members of Spring Bank's Board of Directors, alleging violations of Section 14(a) of the Exchange Act and Rule 14a-9 promulgated thereunder, and as against the individual defendants, alleging violations of Section 20(a) of the Exchange Act. The plaintiff alleges that the defendants made materially misleading disclosures in the Form S-4 by allegedly omitting material information with respect to (i) financial projections relating to Spring Bank and F-star Ltd, (ii) Ladenburg's fairness opinion and (iii) the process relating to the Exchange. The plaintiff in Nowakowski sought rescissory damages against the defendants; declaration that defendants violated Sections 14(a) and 20(a) of the Exchange Act, and Rule 14a-9 promulgated thereunder; and attorneys' and experts' fees. This complaint was voluntarily dismissed on January 11, 2021.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any material litigation.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

The Company's common stock began trading on The Nasdaq Capital Market on May 6, 2016. Prior to the share exchange transaction between Spring Bank and F-star Therapeutics Limited, the common stock traded under the symbol "SBPH" and following the closing of the transaction on November 20, 2020, the common stock now trades under the symbol "FSTX".

Holders of Record

As of March 24, 2021, we had 9,100,320 outstanding shares of common stock and no outstanding shares of preferred stock. At March 24, 2021, there were 156 holders of record of our common stock. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of beneficial holders represented by these record holders.

Sales of Unregistered Securities

In September 2019 Spring Bank issued to certain lenders warrants to purchase 62,500 shares of common stock (the "Pontifax Warrants"). The Pontifax Warrants were exercisable at an exercise price of $8.32 per share and expire on September 19, 2025. At December 31, 2020 the Company has total warrants outstanding to purchase 144,384 shares of common stock at exercise prices ranging from $8.32 to $60.00 per share.

In December 2020 we issued 29,940 restricted shares of common stock to a professional services firm.

Issuer Purchases of Equity Securities

Not applicable.

Item 6. Selected Financial Data.

The following selected consolidated financial data should be read together with our consolidated financial statements and accompanying notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appended to this Annual Report on Form 10-K. The selected consolidated financial data in this section are not intended to replace our consolidated financial statements and the related notes. Our historical results are not necessarily indicative of the results that may be expected in the future.

The selected consolidated statement of operations and consolidated balance sheet data for the years ended December 31, 2020 and 2019 are derived from our audited consolidated financial statements appended to this Annual Report on Form 10-K (in thousands, except share and per share data).

	Year Ended December 31,	
Consolidated Statement of Operations Data:	**2020**	**2019**
License revenue	$ 11,256	$ 28,321
Operating expenses:		
Research and development	14,128	31,386
General and administrative	19,513	15,280
Impairment on intangible assets	—	4,152
Total operating expenses	33,641	50,818
Loss from operations	(22,385)	(22,497)
Other non-operating income (expense):		
Other (expense) income	(849)	197
Change in fair value of convertible debt	(2,386)	(1,450)
Loss before income taxes	(25,620)	(23,750)
Income tax benefit	1	737
Net loss	$ (25,619)	$ (23,013)
Net loss attributable to common shareholders	$ (25,619)	$ (23,013)
Basic and diluted adjusted net loss per common share	$ (9.69)	$ (14.89)
Weighted-average number of common shares outstanding, basic and diluted	2,643,175	1,545,177

See Notes 16 to our consolidated financial statements included in this Annual Report on Form 10-K for further details on the calculation of basic and diluted net loss per common share.

	As of December 31,	
Consolidated Balance Sheet Data:	**2020**	**2019**
Cash, cash equivalents and marketable securities	$18,526	$ 4,901
Working capital	9,088	(10,868)
Total assets	63,609	38,478
Total liabilities	20,615	29,942
Total stockholders' equity	42,994	8,536

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of financial condition and results of operations together with Item 6 of this Annual Report on Form 10-K titled "Selected Financial Data" and our consolidated financial statements and related notes appended to this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in Item 1A, "Risk Factors" of this Annual Report on Form 10-K.

Overview

F-star Therapeutics Inc (collectively with its subsidiaries, "F-star" or the "Company") is a clinical-stage biopharmaceutical company dedicated to developing next generation immunotherapies to transform the lives of patients with cancer. F-star's goal is to offer patients better and more durable benefits than currently available immuno-oncology treatments by developing medicines that seek to block tumor immune evasion. Through our proprietary tetravalent, bispecific natural antibody (mAb²™) format, F-star's mission is to generate highly differentiated medicines with monoclonal antibody-like manufacturability, good safety and tolerability. With four distinct binding sites in a natural human antibody format, F-star believes our proprietary technology will overcome many of the challenges facing current immuno-oncology therapies, due to the strong pharmacology enabled by tetravalent bispecific binding.

F-star's most advanced product candidate, FS118, is currently being evaluated in a proof-of-concept Phase 2 trial in PD-1/PD-L1 acquired resistance head and neck cancer patients. FS118 is a tetravalent mAb2 bispecific antibody targeting two receptors, PD-L1 and LAG-3, both of which are established pivotal targets in immuno-oncology. Phase 1 data from 43 heavily pre-treated patients with advanced cancer, who have failed PD-1/PD-L1 therapy, showed that administration of FS118 was well-tolerated with no dose limiting toxicities up to 20 mg/kg. In addition, a disease control rate, or DCR, defined as either a complete response, partial response or stable disease, of 49% was observed in 39 evaluable patients receiving dose levels of FS118 of 1mg/kg or greater. In acquired resistance patients, DCR defined as either a complete response, partial response or stable disease was 59% (16 out of 27 patients) and long-term (greater than six months) disease control was observed in six of these patients. We expect to provide an update from the proof-of-concept Phase 2 trial in PD-1/PD-L1 acquired resistance head and neck cancer patients in H1 2022.

F-star's second product candidate, FS120, aims to improve checkpoint inhibitor and chemotherapy outcomes and is a mAb ^{2} bispecific antibody that is designed to bind to and stimulate OX40 and CD137, two proteins found on the surface of T cells that both function to enhance T cell activity. F-star are developing FS120 alone and in combination with PD-1/PD-L1 therapy for the treatment of tumors where PD-1/PD-L1 products are approved and which have co-expression of OX40 and CD137 in the tumor microenvironment, such as gastric and bladder cancer. F-star initiated a Phase 1 clinical trial in patients with advanced cancers in the fourth quarter of 2020 and plan to update on the accelerated dose titration phase of this study in mid-2021.

F-star's third product candidate, FS222, aims to improve outcomes in low PD-L1 expressing tumors and is a mAb ^{2} bispecific antibody that is designed to target both the costimulatory CD137 and the inhibitory PD-L1 receptors, which are co-expressed in a number of tumor types including non-small-cell lung cancer, ovarian cancer and gastrointestinal cancers such as colorectal and esophageal cancer. F-star initiated a Phase 1 clinical trial in patients with advanced cancers for FS222 in late 2020. F-star believes there is a strong rationale to combine FS222 with other anti-cancer agents, including targeted therapy and chemotherapy, and this can be done within the Phase 1 study. F-star expects to report an update in late 2021.

SB 11285 which F-star acquired pursuant to the Transaction with Spring Bank Pharmaceuticals; Inc. as described in the next paragraph is a next generation cyclic dinucleotide STING agonist designed to improve checkpoint

inhibition outcomes as an immunotherapeutic compound for the treatment of selected cancers. F-star are conducting an open-label, dose-escalation Phase 1 clinical trial with SB 11285 as an IV administered monotherapy, and in combination with an anti-PD-L1 antibody, in patients with advanced solid tumors. F-star expects to report an update in mid-2021.

Share Exchange Agreement

On November 20, 2020, F-star Therapeutics, Inc. (the "Company or F-star "), formerly known as Spring Bank Pharmaceuticals, Inc. ("Spring Bank"), completed its business combination (the "Transaction") with F-star Therapeutics Limited ("F-star Ltd") in accordance with the terms of the Share Exchange Agreement, dated July 29, 2020 (the "Exchange Agreement"), by and among the Company, F-star Ltd and the holders of issued shares in the capital stock of F-star Ltd and the holders of convertible notes of F-star Ltd each as set forth therein (each a "Seller", and collectively with holders of F-star Ltd securities who subsequently became parties to the Exchange Agreement, the "Sellers"). Pursuant to the Exchange Agreement, each ordinary share of F-star Ltd outstanding immediately prior to the closing of the Transaction (the "Closing") was exchanged by the Seller that owns such F-star Ltd shares for such number of duly authorized, validly issued, fully paid and non-assessable shares of Company common stock as is equal to the exchange ratio formula determined pursuant to the Exchange Agreement (the "Exchange Ratio"), rounded to the nearest whole share of Company common stock (after aggregating all fractional shares of Company common stock issuable to such Seller). Also, on November 20, 2020, in connection with, and prior to completion of, the Transaction, Spring Bank effected a 1-for-4 reverse stock split of its common stock (the "Reverse Stock Split") and, following the completion of the Transaction, changed its name to F-star Therapeutics, Inc. Following the completion of the Transaction, the business of the Company became the business conducted by F-star, which is a clinical-stage immuno-oncology company focused on cancer treatment through its proprietary tetravalent bispecific antibody programs. Unless otherwise noted, all references to share amounts in this report reflect the reverse stock split.

Under the terms of the Exchange Agreement, at the Closing, Spring Bank issued an aggregate of 4,620,618 shares of its common stock to F-star Ltd stockholders, based on an exchange ratio of 0.1125 shares of the Company's common stock for each F-star Ltd ordinary share, stock option and RSU outstanding immediately prior to the Closing. The exchange ratio was determined through arms-length negotiations between Spring Bank and F-star Ltd pursuant to a formula set forth in the Exchange Agreement.

Pursuant to the Exchange Agreement, immediately prior to the Closing, certain investors in F-star Ltd purchased $15.0 million of F-star Ltd ordinary shares (the "Pre-Closing Financing"). These ordinary shares of F-star Ltd were then exchanged at the Closing for shares of the Company's common stock in the Transaction at the same exchange rate.

Pursuant to the Exchange Agreement, all outstanding options to purchase Spring Bank common stock were accelerated immediately prior to the Closing and each outstanding option with an exercise price greater than the closing price of the stock on the Closing Date was exercised in full and all other outstanding options to purchase Company common stock were cancelled effective as of the Closing Date.

Immediately, following the Reverse Stock Split and the Closing, there were approximately 4,449,559 shares of Spring Bank common stock outstanding. Following the Closing, the F-star Ltd stockholders beneficially owned approximately 53.7% of the combined Company's common stock and the existing stockholders of Spring Bank beneficially owned approximately 46.3% of the Company's common stock outstanding. Concurrently with the execution of the Exchange Agreement, certain officers and directors of Spring Bank and F-star Ltd and certain stockholders of F-star Ltd entered into lock-up agreements (the "Lock-up Agreements"), pursuant to which they agreed to certain restrictions on transfers of any shares of the Company's common stock for the 180-day period following the Closing, other than the shares of the Company's common stock received in exchange for ordinary shares of F-star Ltd subscribed for in the Pre-Closing Financing and pursuant to certain other limited exceptions.

In addition, at the Closing, Spring Bank, F-star Ltd, a representative of Spring Bank stockholders prior to the Closing, and Computershare Trust Company N.A., as the Rights Agent, entered into a STING Agonist Contingent Value Rights Agreement (the "STING Agonist CVR Agreement"). Pursuant to the Exchange Agreement and the STING Agonist CVR Agreement, each pre-Reverse Stock Split share of Company common stock held by stockholders as of the record date on November 19, 2020, immediately prior to the Closing, received a dividend of one contingent value right ("STING Agonist CVR"), payable on a pre-Reverse Stock Split basis, entitling such holders to receive, in connection with certain transactions involving proprietary STimulator of INterferon Genes (STING) agonist compound designated as SB 11285 occurring on or prior to the STING Agonist CVR Expiration Date (as defined below) that result in aggregate Net Proceeds (as defined in the STING Agonist CVR Agreement) at least equal to the Target Payment Amount (as defined below): an aggregate amount equal to the greater of (i) 25% of the Net Proceeds received from all CVR Transactions (as defined in the STING Agonist CVR Agreement) and (ii) an aggregate amount equal to the product of $1.00 and the total number of shares of Company common stock outstanding as of such record date (not to exceed an aggregate amount of $18.0 million) (the "Target Payment Amount").

The CVR payment obligation expires on the later of 18 months following the Closing or the one-year anniversary of the date of the final database lock of the Company's current STING clinical trial (as defined in the STING Agonist CVR Agreement) (the "STING Agonist CVR Expiration Date"). The STING Agonist CVRs are not transferable, except in certain limited circumstances, are not certificated or evidenced by any instrument, do not accrue interest and are not registered with the Securities and Exchange Commission (the "SEC") or listed for trading on any exchange. Until the STING Agonist CVR Expiration Date, subject to certain exceptions, the Company is required to use commercially reasonable efforts to (a) complete the STING Trial and (b) pursue a CVR Transaction. Unless terminated earlier in accordance with its terms, the STING Agonist CVR Agreement became effective upon the Closing will continue in effect until the STING Agonist CVR Expiration Date the payment or all CVR payment amounts are paid pursuant to its terms.

At the Closing, Spring Bank, F-star Ltd, a representative of Spring Bank stockholders prior to the Closing, and Computershare Trust Company N.A., as the Rights Agent, also entered into a STING Antagonist Contingent Value Rights Agreement (the "STING Antagonist CVR Agreement"). Pursuant to the Exchange Agreement and the STING Antagonist CVR Agreement, each share of common stock held by stockholders as of November 19, 2020, immediately prior to the Closing, received a dividend of one contingent value right ("STING Antagonist CVR") entitling such holders to receive, in connection with the execution of a potential development agreement (the "Approved Development Agreement") and certain other transactions involving proprietary STING antagonist compound occurring on or prior to the STING Antagonist CVR Expiration Date (as defined below) equal to: 80% of all net proceeds (as defined in the STING Antagonist CVR Agreement) received by the Company after the Closing pursuant to (i) the Approved Development Agreement, if any, and (ii) all CVR Transactions (as defined in the STING Antagonist CVR Agreement) entered into prior to the STING Antagonist CVR Expiration Date (as defined below).

The CVR payment obligations expire on the seventh anniversary of the Closing (the "STING Antagonist CVR Expiration Date"). The STING Antagonist CVRs are not transferable, except in certain limited circumstances, are not certificated or evidenced by any instrument, do not accrue interest and are not registered with the SEC or listed for trading on any exchange. Until the STING Antagonist CVR Expiration Date, subject to certain exceptions, the Company is required to use commercially reasonable efforts to (a) consummate the Approved Development Agreement to the extent not entered into prior to Closing, (b) to perform the terms of the Approved Development Agreement and (c) pursue CVR Transactions. Unless terminated earlier in accordance with its terms, the STING Antagonist CVR Agreement became effective upon the Closing and will continue in effect until the STING Antagonist CVR Expiration Date or all CVR payment amounts are paid pursuant to its terms.

The acquisition-date fair value of the contingent valuation rights liability represents the future payments that are contingent upon the achievement of sale or licencing for the product candidates. The fair value of the contingent consideration acquired of $2.5 million as of December 31, 2020 is based on the Company's probability-weighted

discounted cash flow assessment that considers probability and timing of future payments. The fair value measurement is based on significant Level 3 unobservable inputs such as the probability of achieving a sale or licensing agreement, anticipated timelines and discount rate. Changes in the fair value of the liability will be recognized in the consolidated statement of operations and comprehensive loss until settlement.

All issued and outstanding F-star Ltd share options granted under F-star's three legacy equity incentive plans became exercisable in full immediately prior to the Closing. At the Closing, all issued share options and restricted stock units granted by F-star Ltd under the F-star Therapeutics Limited 2019 Equity Incentive Plan were replaced by options ("Replacement Options") and awards ("Replacement RSUs"), on the same terms (including vesting), for Company common stock, based on the Exchange Ratio.

The Company's common stock, which was listed on the Nasdaq Capital Market, traded through the close of business on Friday, November 20, 2020 under the ticker symbol "SBPH" and continued trading on the Nasdaq Capital Market, on a post-Reverse Stock Split adjusted basis, under the ticker symbol "FSTX" beginning on Monday, November 23, 2020. Commencing on November 23, 2020, the Company's common stock was represented by a new CUSIP number, 30315R 107. After the Transaction, the Company had approximately $30 million in cash. The combined company is now headquartered out of F-star Ltd existing facilities in Cambridge, U.K. and office in Cambridge, MA.

The Transaction was accounted for as a business combination using the acquisition method of accounting under the provisions of Financial Accounting Standards Board, Accounting Standards Codification ("ASC 805"), Topic 805 "Business Combinations" ("ASC 805"). The Transaction was accounted for as a reverse acquisition with F-star Ltd being deemed the acquiring company for accounting purposes. Under ASC 805, F-star Ltd as the accounting acquirer, recorded the assets acquired and liabilities assumed of Spring Bank Pharmaceuticals, Inc in the Transaction at their fair values as of the acquisition date (Note 4 of the financial statements).

F-star Ltd was determined to be the accounting acquirer based on an analysis of the criteria outlined in ASC 805 and the facts and circumstances specific to the Transaction, including the fact that immediately following the Transaction: (1) F-star Ltd shareholders owned the majority of the voting rights of the combined company; (2) F-star Ltd designated a majority (five of eight) of the initial members of the board of directors of the combined company; and (3) F-star Ltd senior management held the key positions in senior management of the combined company. As a result, upon consummation of the Transaction, the historical financial statements of F-star Ltd became the historical financial statements of the combined organization.

2019 reorganization

On May 7, 2019, F-star Ltd acquired 100% of the issued share capital of F-star Delta Ltd ("Delta"), F-star Beta Ltd ("Beta"), F-star Biotechnologische Forschungs-und Entwicklungsges.m.b.H. ("GmbH"), and F-star Alpha Ltd ("Alpha") (collectively, the "F-star Group Entities").

The shareholdings in the F-star Group Entities were transferred to F-star Ltd in consideration of the issue of new shares in F-star Ltd to the shareholders of Alpha, Beta, Delta and GmbH. The transactions were all enacted on May 7, 2019, in two steps:

1. The shareholders in Delta transferred their shares to F-star Ltd in consideration of receiving new shares in F-star Ltd (corporate reorganization).
2. The shareholders in Beta, GmbH and Alpha transferred their shares to F-star Ltd in consideration of receiving new shares in F-star Ltd (business combination and asset acquisition).

F-star Ltd, the legal acquirer of the F-star Group Entities, was an entity with no historical operations and was created solely for the purpose of effecting the corporate reorganization. Accordingly, it was not deemed substantive nor the accounting acquirer of the F-star Group Entities. The initial transaction was therefore

accounted for as a reverse acquisition with Delta subsequently obtaining a controlling interest in GmbH and Beta, and a controlling interest in Alpha through asset acquisition. The effect of the reverse acquisition accounting is that the financial statements to the date of consolidation (May 7, 2019) reflect the operations, historical financial position and financial performance of Delta.

The primary reason for the 2019 reorganization was to bring the F-star Group Entities under common ownership of a holding company to enable management to enact its financial strategy of listing the share capital of F-star Ltd on a public exchange.

Impact of Covid-19 on our Business

In March 2020, the World Health Organization declared the novel strain of coronavirus (COVID-19) a pandemic and recommended containment and mitigation measures worldwide. The COVID-19 pandemic has been evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures.

Management continues to closely monitor the impact of the COVID-19 pandemic on all aspects of the business, including how it will impact operations and the operations of customers, vendors, and business partners. Management took action in April 2020 to temporarily furlough some of its workforce and took advantage of the UK Government Coronavirus Job Retention Scheme (CJRS) that provided funding to businesses with furloughed staff. The grant funding available covered 80% of furloughed employees' wages plus employer National Insurance and pension contributions up to a maximum of £2,500 per month per furloughed employee. The onset of the global pandemic resulted in a three to six-month delay in the operationalization of its clinical trials for FS118, FS120, FS222 and SB 11285. The extent to which COVID-19 impacts the future business, results of operation and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence at this time, such as the continued duration of the outbreak, new information that may emerge concerning the severity or other strains of COVID-19 or the effectiveness of actions to contain COVID-19 or treat its impact, among others. If the Company or any of the third parties with which it engages, however, were to experience shutdowns or other business disruptions, the ability to conduct business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on business, results of operation and financial condition. The estimates of the impact on the Company's business may change based on new information that may emerge concerning COVID-19 and the actions to contain it or treat its impact and the economic impact on local, regional, national, and international markets.

Management have not identified any triggering events which would result in any significant impairment losses in the carrying values of assets as a result of the pandemic and are not aware of any specific related event or circumstance that would require management to revise estimates reflected in our consolidated financial statements.

Financial Operations Overview

License revenue

To date, we have not generated any revenue from product sales, and we do not expect to generate any revenue from product sales for the foreseeable future. Our revenue consists of collaboration revenue under our license and collaboration agreements with Ares, and Denali, including amounts that are recognized related to upfront payments, milestone payments, option exercise payments, and amounts due to us for research and development services. In the future, revenue may include new collaboration agreements, additional milestone payments, option exercise payments, and royalties on any net product sales under our collaborations. We expect that any revenue we generate will fluctuate from period to period as a result of the timing and amount of license, research and development services, and milestone and other payments.

Operating Expenses

Research and development costs

Research and development costs are expensed as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including salaries, share-based compensation and benefits, facilities costs and laboratory supplies, depreciation, amortization and impairment expense, manufacturing expenses and external costs of outside vendors engaged to conduct preclinical development activities and clinical trials as well as the cost of licensing technology. Typically, upfront payments and milestone payments made for the licensing of technology are expensed as research and development in the period in which they are incurred, except for payments relating for intellectual property rights with future alternative use which will be expensed when the intellectual property is in use. Non-refundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Those expenses associated with R&D and clinical costs primarily include:

- expenses incurred under agreements with contract research organizations (“CROs”) as well as investigative sites and consultants that conduct F-star’s clinical trials, preclinical studies and other scientific development services;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial materials;
- expenses incurred for outsourced professional scientific development services;
- costs for laboratory materials and supplies used to support F-star’s research activities;
- allocated facilities costs, depreciation, and other expenses, which include rent and utilities;
- up-front, milestone and management fees for maintaining licenses under F-star’s third-party licensing agreement; and
- compensation expense

The Company recognizes external R&D costs based on an evaluation of the progress to completion of specific tasks using information provided to it by its internal program managers and service providers.

Research and development activities are central to the Company’s business models. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials. As a result, the Company expects that research and development expenses will increase over the next several years as the Company increases personnel costs, initiate and conduct additional clinical trials and prepare regulatory filings related to the various product candidates.

The successful development of our product candidates is highly uncertain. As such, at this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the remainder of the development of these product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from our product candidates. This is due to the numerous risks and uncertainties associated with developing products, including the uncertainty of:

- completing research and preclinical development of our product candidates, including conducting future clinical trials of FS118, FS120, FS222 and SB 11285;
- progressing the preclinical and clinical development of FS118, FS120, FS222 and SB 11285;
- establishing an appropriate safety profile with IND-enabling studies to advance our preclinical programs into clinical development;

- identifying new product candidates to add to our development pipeline;
- successful enrolment in, and the initiation and completion of clinical trials;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- commercializing the product candidates, if and when approved, whether alone or in collaboration with others;
- establishing commercial manufacturing capabilities or making arrangements with third party manufacturers;
- the development and timely delivery of commercial-grade drug formulations that can be used in our clinical trials;
- addressing any competing technological and market developments, as well as any changes in governmental regulations;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations under such arrangements;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how, as well as obtaining and maintaining regulatory exclusivity for our product candidates;
- continued acceptable safety profile of the drugs following approval; and
- attracting, hiring, and retaining appropriately qualified personnel.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, the FDA, EMA or another regulatory authority may require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or we may experience significant trial delays due to patient enrolment or other reasons, in which case we would be required to expend significant additional financial resources and time on the completion of clinical development. In addition, we may obtain unexpected results from our clinical trials and we may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success.

General and administrative expenses

General and administrative expenses consist primarily of salaries, related benefits, travel, and share-based compensation expense for personnel in executive, finance, legal and administrative functions. General and administrative expenses also include facility-related costs, patent filing and prosecution costs, insurance and marketing costs and professional fees for legal, consulting, accounting, audit, tax services and costs associated with being a public company. Other expense also includes foreign currency transaction losses. The Company expects that general and administrative expenses will increase in the future as the Company expands its operating activities and incurs the costs of being a US public company.

Other income and expenses, net

Other income and expenses, net, is primarily rent received from subletting an office in the U.S. and interest received on overdue trade receivable balances, bank interest received, and interest expense, which is primarily bank interest payable and similar charges, the interest liability on leased assets and convertible debt notes, and foreign exchange losses incurred. Foreign exchange gain (loss) is foreign exchange gains or losses due to the fluctuation of GBP, U.S. dollar and the Euro. Change in the fair value of convertible debt is the fair value adjustment of the convertible notes as measured using level 3 inputs.

Benefits from income tax

For the years ended December 31, 2020, and 2019, the Company was subject to corporate taxation in the United States, United Kingdom and Austria.

The UK-established entities have generated losses and some profits in the United Kingdom since inception and have therefore not paid significant United Kingdom corporation tax. F-star GmbH has historical losses in Austria with more recent profits, which has resulted in payment of Austrian corporation tax in the periods ended December 31, 2020 and 2019. The corporation tax benefit/ (tax) presented in the Company's statements of comprehensive income/(loss) represents the tax impact from its operating activities in the United States, United Kingdom and Austria, which has generated taxable income in certain periods. As the entities located in the United Kingdom carry out extensive research and development activities, they seek to benefit from the United Kingdom research and development tax credit cash rebate regime: The Small and Medium-sized Enterprises R&D Tax Credit Program ("SME Program"). Qualifying expenditures largely comprise employment costs for research staff, consumables expenses incurred under agreements with third parties that conduct research and development, preclinical activities, clinical activities and manufacturing on the Company's behalf and certain internal overhead costs incurred as part of research projects. No research and development activities are carried out in Austria and so the Company is not able to utilize the research and development premium available under the Austrian corporation tax regime.

The Small and Medium-sized Enterprises research and development tax credit received in the United Kingdom permits companies to deduct an extra 130% of their qualifying costs from their yearly profit or loss, as well as the normal 100% deduction, to make a total 230% deduction. If the company is loss making it is entitled to claim a tax credit worth up to 14.5% of the surrenderable loss. To qualify for SME research & development relief companies are required to employ fewer than 500 staff and have a turnover of under €100.0 million or a balance sheet total of less than €86.0 million.

The U.K. Government has released draft legislation to introduce a cap on the amount of the payable credit that a qualifying loss-making SME business can receive through R&D relief in any one year. The cap would be applied to restrict payable credit claims in excess of £20,000 with effect for accounting periods beginning on or after April 2021 by reference to, broadly, three times the total employee payroll tax and social security liabilities of the company. The draft legislation also contains an exemption which prevents the cap from applying. That exemption requires the company to be creating, or taking steps to create, intellectual property as well as having research and development expenditure in respect of connected parties which does not exceed 15% of the total claimed. The company does not expect this legislation if adopted to have a material impact on its payable credit claims based on amounts currently claimed.

Research and development tax credits received in the U.K. are recorded as a reduction to research and development expenses. The U.K. research and development tax credit is payable to the Company after surrendering tax losses and is not dependent on current or future taxable income. As a result, it is not reflected as part of the income tax provision. If, in the future, any U.K. research and development tax credits generated are utilized to offset a corporate income tax liability in the U.K., that portion would be recorded as a benefit within the income tax provision and any refundable portion not dependent on taxable income would continue to be recorded as a reduction to research and development expenses.

Income tax benefit decreased by $0.7 million from a tax benefit of $0.7 million to an immaterial tax charge in the year ended December 31, 2020. This increase is due to a $0.9 million movement in the deferred tax liability in the year ended December 31, 2019, with no such movement during 2020, offset by a $0.2 million income tax charge.

In the event the Company generates revenues in the future, the Company may benefit from the United Kingdom "patent box" regime that allows profits attributable to revenues from patents or patented products to be taxed at an effective rate of 10%.

Value Added Tax ("VAT") is broadly charged on all taxable supplies of goods and services by VAT-registered businesses. In the United Kingdom, under current rates, an amount of 20% of the value, as determined for VAT purposes, of the goods or services supplied is added to all sales invoices and is payable to the UK's tax authority, HMRC. Similarly, VAT paid on purchase invoices is generally reclaimable from HMRC. In Austria, under current rates, an amount of 20% of the value, as determined for VAT purposes, of the goods or services supplied is added to all sales invoices and is payable to the Austrian tax authority. Similarly, VAT paid on purchase invoices is generally reclaimable from the Austrian tax authority.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of our consolidated financial statements and related disclosures requires our management to make estimates and assumptions that affect the reported amount of assets, liabilities, revenue, costs and expenses and related disclosures. We believe that the estimates and assumptions underlying the accounting policies described therein may have the greatest potential impact on our consolidated financial statements and, therefore, consider these to be our critical accounting policies. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these current estimates based on different assumptions and under different conditions.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for services performed, on a predetermined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- CROs in connection with performing research services on our behalf and clinical trials;
- investigative sites or other providers in connection with clinical trials;
- vendors in connection with preclinical and clinical development activities; and
- vendors related to product manufacturing, development and distribution of preclinical and clinical supplies.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or amount of prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

Contingent value rights

The acquisition-date fair value of the contingent valuation rights liability represents the future payments that are contingent upon the achievement of sale or licensing for the STING product candidates. The fair value of the contingent value rights is based on the Company's probability-weighted discounted cash flow assessment that considers probability and timing of future payments. The fair value measurement is based on significant Level 3 unobservable inputs such as the probability of achieving a sale or licensing agreement, anticipated timelines, and discount rate. Changes in the fair value of the liability will be recognized in the consolidated statement of operations and comprehensive loss until settlement.

Share-based compensation

The Company accounts for share-based compensation in accordance with ASC 718, 'Compensation – Stock Compensation" ("ASC 718"). ASC 718 requires companies to estimate the fair value of equity-based payment awards on the date of grant. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service period in the Company's consolidated statements of operations and comprehensive loss.

The Company records the expense for option awards using a graded vesting method. The Company accounts for forfeitures as they occur. For share-based awards granted to non-employee consultants, the measurement date is the date of grant. The compensation expense is then recognized over the requisite service period, which is the vesting period of the respective award.

The fair value of stock options ("options") on the grant date is estimated using the Black-Scholes option-pricing model using the single-option approach. The Black-Scholes option pricing model requires the use of highly subjective and complex assumptions, including the option's expected term and the price volatility of the underlying stock, to determine the fair value of the award.

Historically given the absence of an active market for the ordinary shares of F-star Ltd, the board of directors determined the estimated fair value of the Company's equity instruments based on input from management, which utilized the most recently available independent third-party valuation, and considering a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector. Each valuation methodology includes estimates and assumptions that require judgment. These estimates and assumptions include a number of objective and subjective factors in determining the value of F-star Ltd ordinary shares at each grant date. The expected volatility for F star Ltd was calculated based on reported volatility data for a representative group of publicly traded companies for which historical information was available. The historical volatility is calculated based on a period of time commensurate with the assumption used for the expected term. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected term assumption. F-star Ltd TL used the simplified method, under which the expected term is presumed to be the midpoint between the vesting date and the end of the contractual term. F-star Ltd utilized this method due to the lack of historical exercise data and the plain nature of its share-based awards.

The Company uses the remaining contractual term for the expected life of non-employee awards. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends.

The Company classifies share-based compensation expense in its consolidated statements of operations and comprehensive loss Income in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019 (in thousands):

	Years Ended December 31,		
	2020	2019	Change
	(in thousands)		
Statements of Comprehensive Income			
License revenue	$ 11,256	$ 28,321	($17,065)
Operating expenses:			
Research and development	(14,128)	(31,386)	17,258
General and administrative	(19,513)	(15,280)	(4,233)
Impairment of intangible asset	—	(4,152)	4,152
Total operating expenses	**(33,641)**	**(50,818)**	**17,177**
Loss from operations	**(22,385)**	**(22,497)**	**112**
Other non-operating (expense) income:			
Other (expense) income, net	(849)	197	(1,046)
Change in fair value of convertible notes	(2,386)	(1,450)	(936)
Loss before income taxes	**(25,620)**	**(23,750)**	**(1,870)**
Income tax benefit	1	737	(736)
Net loss	**($ 25,619)**	**($ 23,013)**	**($ 2,606)**

License Revenue

Revenue for the year ended December 31, 2020 was $11.3 million, compared with $28.3 million in the comparative year, a decrease of approximately $17.0 million.

The 2019 revenue includes F-star Delta only to May 6, 2019, then all F-star Group Entities from May 7, 2019 to December 31, 2019. For the years ending December 31, 2020 and 2019 revenue has been generated from two collaboration partners (Ares and Denali).

	Years Ended December 31,		
Revenue by collaboration partner	2020	2019	Change
	(in thousands)		
Ares	$ 9,930	$25,871	($15,941)
Denali	1,326	2,450	(1,124)
Total	**$11,256**	**$28,321**	**($17,065)**

Revenue from contracts with Ares decreased by $15.9 million from the year ended December 31, 2019 to December 31, 2020. Revenue of $25.9 million for the year ended December 31, 2019, included $13.3 million related to licensing revenue and R&D services from the 2017 License and Collaboration agreement (“2017 LCA”) with Ares which did not occur in 2020. $1.4 million from the amended License and Collaboration Agreement entered into on May 13, 2019 (“2019 LCA”) was recognised in both the year ended December 31, 2020 and the year ended December 31, 2019.

On entry into the 2019 LCA a $11.2 million option fee was also recognized, which is $2.6 million higher than the option fee recognized on July 15, 2020, on entry into an amendment in respect of the 2019 LCA between the Company and Ares ("2020 LCA").

The remaining decrease in overall revenue of $1.1 million relates in part to $1.5 million paid by Denali during the year ended December 31, 2019 on achievement of a development milestone that related to the first molecule in the collaboration (Fcab#1). This was partially offset by an increase of $0.4 million in R&D services income in relation to the second molecule in the collaboration (Fcab#2), due to increased FTE utilization.

Research and development costs

The table below summarizes our costs related to research and development expense for the year by program:

	Years Ended December 31,		
	2020	2019	Change
Research and development costs by program	(in thousands)		
FS118	$ 3,196	$11,533	($ 8,337)
FS120	3,059	7,684	(4,625)
FS222	5,348	6,311	(963)
Other	2,525	5,858	(3,333)
Total research and development costs by program	**$14,128**	**$31,386**	**($17,258)**

Costs related to research and development for the year ended December 31, 2020 decreased approximately $17.3 million to $14.1 million from $31.4 million in the year ended December 31, 2019.

FS118 costs decreased by $8.3 million from $11.5 million in the year ended December 31, 2019 to $3.2 million in the year ended December 31, 2020. This decrease was primarily due to a decrease in clinical trial CRO costs, associated clinical sampling costs and other R&D costs of $4.1 million, $1.6 million, and $0.9 million respectively, due to a small number of patients remaining on study during 2020 as the Phase 1a trial came to an end. Manufacturing costs also decreased by $2.3 million due to a manufacturing batch run in 2019 that did not occur in 2020. These decreases were partly offset by an increase of $0.3 million of internal costs, mainly due to an increase in FTE utilization from the prior year and a proportion of the $3.3 million decrease in the UK R&D tax incentive from the year ended December 31, 2019 which was allocated across all programs.

FS120 program costs decreased by $4.6 million from $7.7 million in the year ended December 31, 2019 to $3.1 million in the year ended December 31, 2020. This was due to a decrease in $0.9 million of toxicology costs, due to drug safety studies carried out in 2019, a decrease of $4.9 million in manufacturing costs due to a manufacturing batch in 2019 that did not occur in 2020, and a decrease in other R&D costs of $0.7 million due to the timing of development activities. These decreases are offset by an increase in clinical CRO costs of $0.8 million, due to the start-up costs incurred for the planned Phase 1 clinical trial and an increase of internal costs of $1.1 million, mainly due to an increase in FTE utilization from the prior year and the decrease in the UK research and development tax credit in the year from 2019 to 2020.

FS222 program costs decreased by $1.0 million from $6.3 million in the year ended December 31, 2019 to $5.3 million in the year ended December 31, 2020. This was due to a decrease in $1.1 million of toxicology costs, due to drug safety studies carried out in 2019, a decrease of $1.3 million in manufacturing costs, due to a manufacturing batch spanning the 2019 yearend, with most of the cost being recognised in the year ended December 31, 2019, and a decrease in other R&D costs of $0.7 million, due to the timing of development activities. These decreases are offset by an increase in clinical CRO costs of $1.0 million, due to the start-up costs incurred for the Phase 1 clinical trial and an increase of internal costs of $1.1 million, which is mainly due to an increase in FTE utilization from the prior year and the decrease in the UK research and development tax credit in the year from 2019 to 2020.

Other project costs have decreased by $3.3 million from $5.8 million in the year ended December 31, 2019 to $2.5 million in the year ended December 31, 2020. This was primarily due to external expenditures of $2.0 million in 2019 for an early-stage program that was discontinued in 2019 and a decrease of $0.3 million in platform technology expenditure. Allocated costs decreased by $1.0 million from the year ended December 31, 2019, mainly due to a decrease in FTE utilization from the prior year.

The Company begins to separately track program expenses at candidate nomination, at which point the Company accumulates all costs to support that program to date. Through December 31, 2020, since candidate nomination of FS118, FS120 and FS222, the F-star entities have collectively incurred approximately $38.8 million, $15.5 million and $15.7 million, respectively, of expenses for the development of these programs.

General and administrative expense

General and administrative expense for the year ended December 31, 2020 increased by approximately $4.2 million to $19.5 million from $15.3 million for the year ended December 31, 2019. The increase was primarily due to an increase of $2.1 million in compensation related costs and share based compensation expense due to new stock option grants in 2020, $1.5 million in professional fees associated with the November 20, 2020 Share Exchange Agreement, facility/infrastructure costs of $0.9 million and other costs of $0.5 million, primarily due to the acquisition of GmbH Group by F-star Ltd on May 6, 2019, which results in a partial year of costs in 2019, but a full year in 2020, offset by a decrease of $0.8 million relating to a reduction in travel and conferences expenditure, primarily due to COVID-19-related travel restrictions.

Other (expense) and income, net

	Year Ended December 31,		
	2020	2019	Change
	(in thousands)		
Other (expense) income, net			
Other (expense) income, net	($ 849)	$ 197	($1,046)
Change in fair value of convertible notes	(2,386)	(1,450)	(936)
Total other (expense) income, net	**($ 3,235)**	**($ 1,253)**	**($1,982)**

Other (expense) income, net for the year ended December 31, 2020 consisted of net other expenses of $0.8 million compared with net other income of $0.2 million for the year ended December 31, 2019, for an increase of $1.0 million additional net expense. This increase is due to $0.8 million additional interest expense relating to the convertible notes and a foreign currency exchange loss of $0.8 million, both offset by other income of $0.6 million relating to UK government grants received under the Coronavirus Job Retention Scheme (“CJRS”) for the costs of staff furloughed due to the coronavirus (COVID-19) global pandemic.

The loss generated from fair value adjustments increased by $0.9 million from $1.5 million for the year ended December 31, 2019 to $2.4 million in the year ended December 31, 2020. This increase was due to updates to assumptions in the level 3 inputs included in the valuation model at December 31, 2019 compared to the conversion date of November 20, 2020.

Liquidity and Capital Resources

Sources of liquidity

From our inception through December 31, 2020, we have not generated any revenue from product sales, and we have incurred significant operating losses and negative cash flows from our operations. We do not expect to generate significant revenue from sales of any products for several years, if at all.

At December 31, 2020, the Company had working capital (current assets less current liabilities) of $9.1 million, an accumulated deficit of $47.2 million, cash of $18.5 million and accounts payable and accrued expenses of $14.1 million. The future success of the Company is dependent on its ability to successfully obtain additional working capital, obtain regulatory approval for and successfully launch and commercialize its product candidates and to ultimately attain profitable operations.

Historically, we have financed our operations primarily with proceeds from the issuance of ordinary and convertible preferred shares, proceeds from issuances in connection with a convertible note facility, proceeds received from upfront payments and development milestone payments in connection with our collaboration arrangements, and payments received for research and development services. We expect this historical financing trend to continue if and until we are able obtain regulatory approval for and successfully commercialize one or more of our drug candidates, although there can be no assurance that we will obtain regulatory approval or successfully commercialize any of our current or planned future product candidates.

Cash Flows

The following table summarizes our cash flows for each of the years presented:

	Years Ended December 31,		
	2020	2019	Change
	(in thousands)		
Net cash (used) provided in operating activities	($16,226)	($22,111)	$ 5,885
Net cash provided by investing activities	14,049	5,372	8,677
Net cash provided by financing activities	15,850	13,264	2,586
Effect of exchange rate changes on cash	(48)	180	(228)
Net increase (decrease) in cash	**$ 13,625**	**($ 3,295)**	**$16,920**

Operating activities

Net cash used of $16.3 million in operating activities for the year ended December 31, 2020 consisted of the net loss of $25.6 million adjusted for changes in our operating assets and liabilities of $1.1 million and non-cash charges of $8.4 million, which primarily included share-based compensation expense of $3.5 million, interest expense of $1.0 million, depreciation of $1.1 million, changes in the fair value of the convertible note of $2.4 million and foreign exchange loss and other of $0.4 million.

Net cash used of $22.1 million in operating activities for the year ended December 31, 2019 was primarily due to a net loss of $23.0 million offset by $9.4 million of non-cash items for share based compensation, depreciation, changes in fair value of convertible notes and the impairment of intangible assets. In addition, there was $8.5 million cash used due primarily to a decrease in tax receivable and a decrease in deferred revenues offset by an increase in accounts payable and accrued expenses.

Investing activities

For the year ended December 31, 2020 and 2019, cash provided from investing activities were $14.0 and $5.4 million, respectively. For the year ended December 31, 2020, this consisted of $9.8 million of cash assumed in the Transaction and $5.0 million on sale of marketable securities relating to the Transaction, offset by $0.7 million for the purchase of certain intangible assets.

The $5.4 million cash provided from investing activities for the year ended December 31, 2019 primarily consisted of cash acquired relating to the May 6, 2019 reorganization.

Financing activities

During the year ended December 31, 2020, net cash provided by financing activities were primarily related to $15.0 million of cash received in exchange for the issue of shares in F-star Ltd prior to the Transaction and $0.9 million for the issue of convertible notes prior to the Transaction.

During the year ended December 31, 2019 net cash provided by financing activities was $13.3 million which was entirely due to the issue of convertible notes in F-star Ltd.

Funding Requirements

Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The accompanying financial statements do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if the Company is unable to continue as a going concern. The Company expects its costs and expenses to increase as it continues to develop its product candidates and progress its current clinical programs and cost associated with being a public company.

Pursuant to the requirements of Accounting Standard Codification (ASC) 205-40, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date of these financial statements, and (1) is probable that the plan will be effectively implemented within one year after the date the financial statements are issued, and (2) it is probable that the plan, when implemented, will mitigate the relevant condition or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date the financials are issued. Certain elements of the Company's operating plan to alleviate the conditions that raise substantial doubt are outside of the Company's control and cannot be included in management's evaluation under the requirements of Accounting Standard Codification (ASC) 205-40.

The Company has incurred significant losses and has an accumulated deficit of $47.2 million as of December 31, 2020. F-star expects to incur substantial losses in the foreseeable future as it conducts and expands its research and development activities. As of March 30, 2021, the date of issuance of the consolidated financial statements, the Company's current cash deposits will not be sufficient to fund its current operating plan and planned capital expenditures for at least the next 12 months. These conditions give rise to a substantial doubt over the Company's ability to continue as a going concern.

The Company intends to seek additional funding through public equity, private equity, debt financing, collaboration partnerships, or other sources. There are no assurances, however, that the Company will be successful in raising additional working capital, or if it is able to raise additional working capital, it may be unable to do so on commercially favorable terms. The Company's failure to raise capital or enter into other such arrangements if and when needed would have a negative impact on its business, results of operations and financial condition and its ability to develop its product candidates.

Our future capital requirements will depend on many factors, including:

- our ability to raise capital in light of the impacts of the ongoing global COVID-19 pandemic on the global financial markets;
- the scope, progress, results, and costs of drug discovery, preclinical development, laboratory testing, and clinical trials for the product candidates we may develop;

- our ability to enrol clinical trials in a timely manner and to quickly resolve any delays or clinical holds that may be imposed on our development programs, particularly in light of the global COVID-19 pandemic;
- the costs associated with our manufacturing process development and evaluation of third-party manufacturers and suppliers;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of preparing and submitting marketing approvals for any of our product candidates that successfully complete clinical trials, and the costs of maintaining marketing authorization and related regulatory compliance for any products for which we obtain marketing approval;
- the costs of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights, and defending intellectual property-related claims;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing, and distribution, for any product candidates for which we receive marketing approval;
- the terms of our current and any future license agreements and collaborations; and the extent to which we acquire or in-license other product candidates, technologies and intellectual property.
- the success of our collaborations with Ares and Denali and other partners;
- our ability to establish and maintain additional collaborations on favorable terms, if at all; and
- the costs of operating as a public company.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

Recently Issued Accounting Pronouncements

In December 2019, the FASB issued ASU No. 2019-12, “Income Taxes—Simplifying the Accounting for Income Taxes.” The ASU simplifies the accounting for income taxes by removing certain exceptions to the general principles as well as clarifying and amending existing guidance to improve consistent application. The amendments to this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. Depending on the amendment, adoption may be applied on the retrospective, modified retrospective or prospective basis. The Company is currently evaluating the impact to the consolidated financial statements.

Emerging Growth Company and Smaller Reporting Company Status

We are an “emerging growth company,” or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, We will remain an EGC until the earlier of (1) the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering (December 31, 2021), (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (3) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our ordinary shares held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such fiscal year or (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. The JOBS Act permits an EGC to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to “opt out” of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

In addition, we intend to rely on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, we are entitled to rely on certain exemptions as an “emerging growth company,” we are not required to, among other things, (i) provide an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b), (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that has or may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements (auditor discussion and analysis), and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer’s compensation to median employee compensation. These exemptions will apply for a period of five years following the completion of our IPO (December 31, 2021) or until we no longer meet the requirements of being an emerging growth company, whichever is earlier.

We are also a smaller reporting company as defined in the Securities Exchange Act of 1934, as amended. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. Our cash, cash equivalents and marketable securities of $18.5 million as of December 31, 2020 consisted of cash, cash equivalents and marketable securities. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because a significant amount of the marketable securities in our investment portfolio are short-term in nature, an immediate 10% change in market interest rates would not be expected to have a material impact on the fair market value of our investment portfolio or on our financial condition or results of operations.

Item 8. Financial Statements and Supplementary Data.

The financial statements required by this item are set forth beginning on page F-1 of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of December 31, 2020, our management, under the supervision of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's (the "SEC") rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of December 31, 2020, because of the material weaknesses in internal control over financial reporting described below.

Management's Annual Report on Internal Control over Financial Reporting

We have performed an evaluation of the effectiveness of our internal control over financial reporting, based on criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 Internal Control-Integrated Framework. Based on that evaluation, our management, including our Chief Executive Officer and Chief Financial Officer, concluded that our internal control over financial reporting was not effective as of December 31, 2020, due to material weaknesses in internal control over financial reporting, associated (i) the lack of formal policies and procedures and sufficient complement of personnel to implement effective segregation of duties and (ii) the company did not have sufficient formality and evidence of controls over key reports and spreadsheets.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to

future years are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As an “emerging growth company” under the Jumpstart Our Business Startups Act, we are exempt from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002. As a result, PricewaterhouseCoopers LLP, our independent registered public accounting firm, has not audited or issued an attestation report with respect to the effectiveness of our internal control over financial reporting as of December 31, 2020.

Remediation Plans

As discussed above, the material weaknesses over effective controls on the financial statement close and reporting process as well as lack of an effective control environment with formal processes and procedures and not having sufficient formality and evidence of controls as of December 31, 2019, were not remediated during 2020. We have commenced measures to remediate these material weaknesses and have hired additional finance and accounting personnel during the fourth quarter of 2020 with appropriate expertise to perform specific functions which we believe will allow for proper segregation of duties, design key controls and implement improved processes and internal controls. We will continue to assess our finance and accounting staffing needs to ensure remediation of these material weaknesses. The material weaknesses will not be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the year ended December 31, 2020, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

UNAUDITED PROFORMA CONDENSED COMBINED FINANCIAL INFORMATION

The following unaudited pro forma condensed combined statements of operations of F-star Therapeutics, Inc., formerly known as "Spring Bank Pharmaceuticals, Inc." (the "Company") for the year ended December 31, 2020 presents the combination of the financial information of F-star Therapeutics Limited (F-star") and Spring Bank Pharmaceuticals, Inc ("Spring Bank") after giving effect to the Business Combination, and related adjustments described in the accompanying notes. F-star and Spring Bank are collectively referred to herein as the "Companies," and the Companies, subsequent to the Business Combination, are referred to herein as the Company.

The unaudited pro forma condensed combined statements of operations for the year ended December 31, 2020 gives proforma effect to the business combination as if the acquisition had occurred on January 1, 2020. These pro forma results exclude the presentation of a pro forma consolidated combined balance sheet. The Company has presented a December 31, 2020 audited consolidated balance sheet in its consolidated financial statements filed within the Form 10-K for the period ended December 31, 2020, which reflects the actual balance sheet impacts of the transaction.

The historical financial statements of Spring Bank and F-star have been adjusted to give pro forma effect to events that are (i) directly attributable to the Exchange, (ii) factually supportable, and (iii) at the date hereof are expected to have a continuing impact on the combined companies' results.

The unaudited pro forma condensed combined financial information, including the notes thereto, should be read in conjunction with the separate historical financial statements of Spring Bank and F-star. The audited consolidated financial statements of Spring Bank are included in Spring Bank's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as filed with the Securities and Exchange Commission (the "SEC") on February 14, 2020 and Spring Bank's unaudited consolidated financial statements as of and for the nine months ended September 30, 2020 and 2019 in the Form 10-Q filed with the SEC on November 3, 2020. F-star's historical audited consolidated financial statements for the years ended December 31, 2020 and 2019 are included in the Company's Annual Report on Form 10-K included herein.

The unaudited pro forma condensed combined financial statements have been presented for illustrative purposes and do not necessarily reflect what the Company results of operations would have been had the share exchange with Spring Bank occurred on the date indicated. Further, the unaudited pro forma condensed combined financial information also may not be useful in predicting the results of operations of the Company. The actual results of operations may differ significantly from the pro forma amounts reflected herein due to a variety of factors. The unaudited pro forma adjustments represent management's estimates based on information available as of the date of these unaudited pro forma condensed combined financial statements and are subject to change as additional information becomes available and analyses are performed.

On November 20, 2020, F-star completed a share exchange agreement with Spring Bank, a NASDAQ- listed, clinical-stage biopharmaceutical company, under the terms of which, each outstanding share of F-star was exchanged for Spring Bank common stock at an exchange ratio of 0.1125. The resulting ownership percentages for Spring Bank shareholders and F-star shareholders immediately as of the closing was 46.3% and 53.7%, respectively.

In the unaudited pro forma condensed combined financial statements, the Exchange was recorded as a business combination using the acquisition method of accounting under accounting principles generally accepted in the United States ("U.S. GAAP"). The Exchange has been accounted for as a reverse acquisition under the accounting guidance and F-star, as the accounting acquirer, recorded the assets acquired and liabilities assumed of Spring Bank in the Exchange at their fair values as of the acquisition date. Note 3 provides additional detail on the accounting for the transaction.

F-STAR THERAPEUTICS, INC.
UNAUDITED PRO FORMA CONDENSED COMBINED
STATEMENT OF OPERATIONS FOR THE YEAR
ENDED DECEMBER 31, 2020
(in thousands, except per share amounts)

	F-star	Spring Bank (1)	Pro Forma Adjustments	Pro Forma Combined	
License revenue	$ 11,256	$ 0	$	$ 11,256	
Operating Expenses:					
Research and development	14,128	12,684		26,812	
General and administrative	19,513	15,088	(9,200)	25,401	A, B, C
Total operating expenses	33,641	27,772	(9,200)	52,213	
Loss from operations	(22,385)	(27,772)	9,200	(40,957)	
Other expense					
Other (expense)	(849)	(1,338)	1,002	(1,185)	D
Change in fair value of liabilities	(2,386)	0	2,386	0	D
Loss before tax	(25,620)	(29,111)	12,588	(42,143)	
Income tax benefit	1	0		1	
Net loss	$ (25,619)	$ (29,111)	$ 12,588	$ (42,142)	
Net loss per share, basic and diluted	$ (9.69)	$ (7.74)		$ (4.77)	E
Weighted-average common shares outstanding, basic and diluted	2,643,175	3,761,161	2,443,911	8,839,247	E

(1) The Spring Bank unaudited statement of operations is for the period January 1, 2020 to November 20, 2020, the date of the transaction. The unaudited financial information to September 30, 2020 was extracted from Spring Bank's unaudited consolidated financial statements as of and for the nine months ended September 30, 2020 in the Form 10-Q filed with the SEC on November 3, 2020. The unaudited financial information from October 1, 2020 to November 20, 2020 was provided by Spring Bank management.

NOTES TO THE UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

All amounts below are in thousands, unless specifically noted otherwise, except share and per share amounts.

1. **Description of the Business Combination**

On November 20, 2020, F-star Therapeutics Limited. ("F-star") completed a share exchange agreement with Spring Bank Pharmaceuticals Inc ("Spring Bank"), a NASDAQ- listed, clinical-stage biopharmaceutical company. Immediately prior to the combination, Spring Bank effectuated a 1:4 reverse stock split of shares of its common stock which equated to 4,449,559 common shares which represented 17,267,202 shares of Spring Bank common stock outstanding as of November 20, 2020, prior the 1:4 stock split and 532,000 shares of restricted common stock that became vested in full upon the closing of the transaction, prior to the 1:4 stock split less the fractional shares which equated to 241 shares which were purchased by F-star for an immaterial amount. Concurrent with the closing of the business combination, each outstanding share of F-star was exchanged for Spring Bank common stock at an exchange ratio of 0.1125. The resulting ownership percentages for Spring Bank shareholders and F-star shareholders immediately as of the closing was 46.3% and 53.7%, respectively. Concurrent with the closing of the combination, an investor syndicate that comprises Atlas, AESCAP, SR One, M Ventures, MH Partners and other new investors, invested $15 million in F-star.

2. **Basis of Presentation**

The accompanying unaudited pro forma condensed combined financial information has been prepared in accordance with SEC Regulation S-X Article 11 in place at the time the Company was required to file a Form 8-K announcing the completion of the transaction. The historical financial information of Spring Bank and F-Star has been adjusted in the unaudited pro forma condensed combined financial information to give effect to events that are (1) directly attributable to the Business Combination, (2) factually supportable, and (3) expected to have a continuing impact on the combined results. The pro forma adjustments are prepared to illustrate the estimated effect of the Business Combination and certain other adjustments.

The unaudited pro forma condensed combined financial information does not reflect the income tax effects of the pro forma adjustments as any change in the deferred tax balance would be offset by an increase in the valuation allowance given that F-star incurred significant losses during the historical periods presented.

3. **Accounting for the Exchange**

On November 20, 2020, F-star Ltd completed its business combination with Spring Bank. For accounting purposes, the purchase price was based on (i) the fair value of Spring Bank common stock as of the Transaction date of $21.5 million which was determined based on the number of shares of common stock in connection with the Transaction, (ii) the portion of the fair value attributable to in the money fully and partially vested stock options and warrants.

Under the acquisition method of accounting, the total purchase price is allocated to the acquired tangible and intangible assets and assumed liabilities based on their fair values as of the acquisition date. Any excess purchase price over the fair value of assets acquired and liabilities assumed is allocated to goodwill. Acquired in-process research and development assets will be classified as indefinite-lived intangible assets and will be amortized over their estimated useful economic lives when put into use. The fair values of acquired in-process research and development assets were calculated using an income approach based on the expected future cash flows associated with the respective asset using an estimated discount rate of 14%. In addition, on the date of the Transaction there were 73,337 outstanding equity classified warrants with a fair value of $0.2 million and 408,444 outstanding liability classified warrants with a fair value of $0.2 million.

Goodwill is allocated to one reporting unit. The goodwill was primarily attributable to the access F-star Ltd gained to the Nasdaq public listing. The Company determined that the underlying goodwill and intangible assets are not deductible for tax purposes.

For the year ended December 31, 2020, the Company incurred acquisition-related expenses of approximately $4.2 million which are included in general and administrative expenses. The purchase price is allocated to the fair value of assets and liabilities acquired as follows:

Number of full common shares	4,449,559
Multiplied by fair value per share of common stock	$ 4.84
Purchase price	$ 21,536
Cash and cash equivalents	$ 9,779
Marketable securities	5,000
Prepaid expenses and other assets	935
Operating lease right of use asset	2,784
Intangible assets	4,720
Goodwill	10,451
Accounts payable, accrued expenses and other liabilities	(5,453)
Contingent value rights	(2,520)
Liability and equity based warrants	(422)
Deferred tax liability	(576)
Operating lease liability	(3,162)
Fair value of net assets acquired	$ 21,536

A liability was recognized for the contingent value rights. Any change in the fair value of the contingent value rights to the acquisition date, including changes from events after the acquisition date, such as changes in our estimate will be recognized in earnings in the period the estimated fair value changes. The fair value estimate for the contingent value rights was estimated at $2.5 million and is based on the probability weighted achieved over the estimated period. The company's estimated range of possible outcomes were up to $26.0 million. A change in fair value of the contingent value rights could have a material effect on the statement of operations and financial position in the period of the change in estimate.

The results of this acquisition were included in the Company's consolidated statement of operations and comprehensive loss beginning on November 20, 2020.

The Company's consolidated net loss for the year ended December 31, 2020, includes a loss of $1.7 million for Spring Bank operations since the Transaction date.

4. **Pro Forma Adjustments**

The unaudited pro forma condensed combined financial statements include pro forma adjustments that are (i) directly attributable to the Exchange, (ii) factually supportable, and (ii) expected to have a continuing impact on the results of operations of the company. The unaudited pro forma condensed combined financial information gives effect to the reverse stock split of Spring Bank common stock, which occurred immediately prior to the Closing. Based on F-star management's review of Spring Bank's summary of significant accounting policies, the nature and amount of any adjustments to the historical consolidated financial statements of Spring Bank to conform to the accounting policies of F-star were not significant. The pro forma adjustments are as follows:

(A) Represents an adjustment to eliminate non-recurring severance costs of $2,700 and transaction costs of $1,800 incurred by Spring Bank in connection with the transaction and recorded as expense in Spring

Bank's historical consolidated statement of operations for the period from January 1, 2020 through November 20, 2020 as these expenses are not expected to have a continuing impact on the operating results of the combined company.

(B) Represents an adjustment to eliminate non-recurring transactional costs of $4,200 incurred by F-star in connection with the transaction and recorded as expense in F-Star's historical consolidated statement of operations for the period from January 1, 2020 through December 31, 2020 as these expenses are not expected to have a continuing impact on the operating results of the combined company.

(C) To record $100 reduction in operating lease expense related to: (1) adjustment straight-line rent expense for cash rent payments over the remaining lease term; and (2) annual amortization of $378 adjustment to the lease right-of-use (ROU) asset for above market rent.

(D) To eliminate interest expense of $1,002 and mark to market adjustments for convertible notes that were converted into F-star common shares immediately before the transaction and then exchanged for Spring Bank shares as part of the transaction.

(E) To reflect the weighted average shares outstanding for the period after giving effect to the issuance of Spring Bank common stock in connection with the transaction. As the combined company is in a net loss position, any adjustment for potentially dilutive shares would be anti-dilutive, and as such basic and diluted loss per share are the same. The following table presents these pro forma adjustments giving effect to the reverse stock split, as follows (presented on a weighted average basis):

	Year Ended December 31, 2020
Weighted average common shares of F-star outstanding, basic and diluted	2,634,175
Weighted average common shares resulting from conversion of F-star Series A preferred shares	143,994
Weighted average common shares resulting from conversion of F-star seed shares	10,350
Weighted average common shares resulting from conversion of F-star convertible notes	1,283,820
Weighted average common shares resulting from F-star pre-close financing	1,005,747
Weighted average shares of Spring Bank Common Stock outstanding during the period January 1, 2020 through November 20, 2020	3,761,161
Pro forma combined weighted average number of common shares outstanding—basic and diluted	8,839,247

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is incorporated by reference from the discussion responsive thereto under the captions “Management and Corporate Governance” and “Code of Business Conduct and Ethics” in our proxy statement for the 2021 annual meeting of stockholders.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference from the discussion responsive thereto under the caption “Executive Officer and Director Compensation” in our proxy statement for the 2021 annual meeting of stockholders.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item is incorporated by reference from the discussion responsive thereto under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” in our proxy statement for the 2021 annual meeting of stockholders.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item is incorporated by reference from the discussion responsive thereto under the captions “Certain Relationships and Related Person Transactions” and “Management and Corporate Governance” in our proxy statement for the 2021 annual meeting of stockholders.

Item 14. Principal Accounting Fees and Services.

The information required by this item is incorporated by reference from the discussion responsive thereto under the caption “Ratification of Selection of Independent Registered Public Accounting Firm” in our proxy statement for the 2021 annual meeting of stockholders.

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PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The financial statements schedules and exhibits filed as part of this Annual Report on Form 10-K are as follows:

(1) Financial Statements

Reference is made to the financial statements included in Item 8 hereof.

(2) Financial Statement Schedules

All other schedules are omitted because they are not required, or the required information is included in the financial statements or notes thereto.

(3) Exhibits

Exhibits. The following is a list of exhibits filed as part of this Annual Report on Form 10-K

Item 16. Form 10-K Summary

Not applicable.

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Exhibit Index

Exhibit Number	Description
2.1	Share Exchange Agreement, dated as of July 29, 2020, by and among Spring Bank Pharmaceuticals, Inc., F-star Therapeutics Limited and the persons listed therein (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed July 30, 2020 (Commission File No. 001-37718))
3.1	Restated Certificate of Incorporation of Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed May 13, 2016 (Commission File No. 001-37718))
3.2	Amended and Restated Bylaws of Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed April 13, 2020 (Commission File No. 001-37718))
3.3	Certificate of Amendment (Reverse Stock Split) to the Amended and Restated Certificate of Incorporation of the Registrant, dated November 20, 2020 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed November 20, 2020 (Commission File No. 001-37718))
3.4	Certificate of Amendment (Name Change) to the Amended and Restated Certificate of Incorporation of the Registrant, dated November 20, 2020) (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed November 20, 2020 (Commission File No. 001-37718))
4.1	Form of Common Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8 filed November 30, 20220 (Commission File No. 333-251033))
4.2	Form of Warrant issued to Dawson James Securities, Inc. (May 2016) (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed May 13, 2016 (Commission File No. 001-37718))
4.3	Form of Warrant to Purchase Common Stock (November 2016) (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed November 21, 2016 (Commission File No. 001-37718))
4.4	Form of Pontifax Warrants issued under the Loan and Security Agreement, dated September 3, 2019 (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-3 filed November 1, 2019 (Commission File No. 333-234436))
4.5	Form of Amended and Restated Warrant (Pontifax) (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed April 13, 2020 (Commission File No. 001-37718))
10.1#	2014 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 filed January 5, 2016 (Commission File No. 333-208875))
10.2#	Form of Incentive Stock Option Agreement under 2014 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 filed January 5, 2016 (Commission File No. 333-208875))
10.3#	Form of Nonstatutory Stock Option Agreement under 2014 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 filed January 5, 2016 (Commission File No. 333-208875))
10.4#	Amended and Restated 2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed June 25, 2020 (Commission File No. 001-37718))

Exhibit Number	Description
10.5#	Form of Incentive Stock Option Agreement under 2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 filed January 5, 2016 (Commission File No. 333-208875))
10.6#	Form of Nonstatutory Stock Option Agreement under 2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 filed January 5, 2016 (Commission File No. 333-208875))
10.7#	Form of Performance-Based Restricted Stock Unit Agreement under 2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.8 to the Registrant's Current Report on Form 10-K filed March 11, 2019 (Commission File No. 001-37718))
10.8#	2019 Equity Incentive Plan and form of agreements thereunder (incorporated by reference to Exhibit 99.1 to the Registrant's Registration Statement on Form S-8 filed November 30, 2020 (Commission File No. 333-251033))
10.9#*	Non-Employee Director Compensation Policy
10.10	Spring Bank Lease Agreement between 35 Parkwood Realty LLC and Spring Bank Pharmaceuticals, Inc., dated October 4, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed October 5, 2017 (Commission File No. 001-37718))
10.11.1	Amendment No. 1 to Lease Agreement between 35 Parkwood Realty LLC and Spring Bank Pharmaceuticals, Inc., dated August 10, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 10-Q filed October 25, 2018 (Commission File No. 001-37718))
10.11.2*	Lease Agreement between Are-Tech Square, LLC and F-star Biotechnology Ltd., dated December 31, 2018.
10.11.3*	Tenancy Agreement between Babraham Bioscience Technologies Limited and F-star Biotechnology Limited, dated February 14, 2018.
10.12#	Executive Service Agreement, dated as of October 1, 2018, as amended July 22, 2020, by and between F-star Biotechnology Limited and Eliot Forster, Ph.D. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on November 20, 2020 (Commission File No. 001-37718))
10.13#	Consulting Agreement, dated as of May 1, 2019, by and between F-star Therapeutics LLC and Darlene Deptula-Hicks (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on November 20, 2020 (Commission File No. 001-37718))
10.14#	Service Agreement, dated as of July 23, 2020, by and between F-star Biotechnology Limited and Neil Brewis, Ph.D. (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on November 20, 2020 (Commission File No. 001-37718))
10.15#	Employment Agreement, dated as of July 24, 2020, by and between F-star Therapeutics LLC and Louis Kayitalire, M.D. (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed on November 20, 2020 (Commission File No. 001-37718))
10.16#	Form of Indemnification Agreement, by and between Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K filed on November 20, 2020 (Commission File No. 001-37718))
10.17	STING Agonist Contingent Value Rights Agreement, dated as of November 20, 2020, by and between Spring Bank Pharmaceuticals, Inc., F-star Therapeutics Limited, Computershare Inc., Computershare Trust Company, N.A., and the Holder Representative (incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K filed on November 20, 2020 (Commission File No. 001-37718))

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Exhibit Number	Description
10.18	STING Antagonist Contingent Value Rights Agreement, dated as of November 20, 2020, by and between Spring Bank Pharmaceuticals, Inc., F-star Therapeutics Limited, Computershare Inc., Computershare Trust Company, N.A., and the Holder Representative (incorporated by reference to Exhibit 10.7 to the Registrant's Current Report on Form 8-K filed on November 20, 2020 (Commission File No. 001-37718))
10.19†	License and Collaboration Agreement, by and among F-star Gamma Limited, F-star GmbH, F-star Biotechnology Limited and Denali Therapeutics Inc., dated as of August 24, 2016 (incorporated by reference to Exhibit 10.29 to the Registrant's Registration Statement on Form S-4/A filed on September 30, 2020 (Commission File No. 333-248487))
10.20†	Side Letter to License and Collaboration Agreement by and among F-star Gamma Limited, F-star GmbH, F-star Biotechnology Limited and Denali Therapeutics Inc., dated May 21, 2018 (incorporated by reference to Exhibit 10.30 to the Registrant's Registration Statement on Form S-4/A filed on September 30, 2020 (Commission File No. 333-248487))
10.21†	Gamma Support Services Agreement, by and between F-star Biotechnology Limited and F-star Gamma Limited, dated August 24, 2016 (incorporated by reference to Exhibit 10.31 to the Registrant's Registration Statement on Form S-4/A filed on September 30, 2020 (Commission File No. 333-248487))
10.22†	Share Purchase Agreement, by and between Denali Therapeutics Inc. and F-star Gamma Limited, dated May 30, 2018 (incorporated by reference to Exhibit 10.32 to the Registrant's Registration Statement on Form S-4/A filed on September 30, 2020 (Commission File No. 333-248487))
10.23†	Agreement, by and between, Iontas Limited and F-star Beta Limited, dated March 6, 2018 (incorporated by reference to Exhibit 10.33 to the Registrant's Registration Statement on Form S-4/A filed on September 30, 2020 (Commission File No. 333-248487))
10.24†	Amended and Restated PD-L1 License Agreement, between F-star Beta Limited and Kymab Limited, dated as of November 26, 2018 (out-license) (incorporated by reference to Exhibit 10.34 to the Registrant's Registration Statement on Form S-4/A filed on September 30, 2020 (Commission File No. 333-248487))
10.25†	Amended and Restated PD-L1 License Agreement, between F-star Beta Limited and Kymab Limited, dated as of November 26, 2018 (in-license) (novated to F-star Delta November 30, 2018) (incorporated by reference to Exhibit 10.35 to the Registrant's Registration Statement on Form S-4/A filed on September 30, 2020 (Commission File No. 333-248487))
10.26†	License and Collaboration Agreement, between F-star Delta Limited, F-star Beta Limited, F-star Biotechnology Limited, F-star GmbH and Ares Trading S.A., dated as of May 13, 2019 (incorporated by reference to Exhibit 10.36 to the Registrant's Registration Statement on Form S-4/A filed on September 30, 2020 (Commission File No. 333-248487))
10.27	Form of Equity Commitment Letter, dated as of, July 29, 2020 (incorporated by reference to Exhibit 10.37 to the Registrant's Registration Statement on Form S-4/A filed on September 30, 2020 (Commission File No. 333-248487))
21.1	Subsidiaries of Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Current Report on Form 10-K filed on February 14, 2020 (Commission File No. 001-37718))
23.1*	Consent of PricewaterhouseCoopers LLP, Independent Auditors of F-star Therapeutics Limited
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

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Exhibit Number	Description
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.
\# Indicates a management contract or compensatory plan, contract or arrangement.
† Confidential treatment has been requested or granted as to certain portions, which portions have been omitted and filed separately with the SEC.
^ Previously Filed.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Company Name

Date: March 30, 2021

By: /s/ Eliot Forster, Ph.D.
Eliot Forster, Ph.D.
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Eliot Forster, Ph.D. Eliot Forster, Ph.D.	Chief Executive Officer and Chairman (*principal executive officer*)	March 30, 2021
/s/ Darlene Deptula-Hicks Darlene Deptula-Hicks	Chief Financial Officer and Treasurer (*principal financial officer and principal accounting officer*)	March 30, 2021
/s/ David Arkowitz David Arkowitz	Director	March 30, 2021
/s/ Edward Benz, Jr., M.D. Edward Benz, Jr., M.D.	Director	March 30, 2021
/s/ Nessan Bermingham, Ph.D. Nessan Bermingham, Ph.D.	Director	March 30, 2021
/s/ Todd Brady, M.D., Ph.D. Todd Brady, M.D., Ph.D.	Director	March 30, 2021
/s/ Pamela Klein, M.D. Pamela Klein, M.D.	Director	March 30, 2021
/s/ Patrick Krol. Patrick Krol	Director	March 30, 2021
/s/ Geoffrey Race Geoffrey Race	Director	March 30, 2021

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Item 8. Consolidated Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

F-star Therapeutics Inc.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of F-star Therapeutics, Inc

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of F-star Therapeutics, Inc and its subsidiaries (the "Company") as of December 31, 2020 and 2019, and the related consolidated statements of operations and comprehensive loss, of stockholders' equity (deficit) and of cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the consolidated financial statements, the Company has incurred significant losses and has an accumulated deficit that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 3. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/PricewaterhouseCoopers LLP
Cambridge, United Kingdom
March 30, 2021

We have served as the Company's or its predecessor's auditor since 2013.

F-star Therapeutics Inc.
Consolidated Balance Sheets
(In Thousands, Except Share and Per Share Amounts)

	December 31, 2020	December 31, 2019
Assets		
Current Assets:		
Cash and cash equivalents	$ 18,526	$ 4,901
Prepaid expenses and other current assets	3,976	3,588
Tax incentive receivable	3,563	10,532
Total current assets	26,065	19,021
Property and equipment, net	789	1,425
Right of use asset	2,782	607
Goodwill	14,926	4,320
In-process research and development	18,986	13,049
Other long-term assets	61	56
Total assets	$ 63,609	$ 38,478
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 4,597	$ 5,056
Accrued expenses and other current liabilities	9,461	8,876
Contingent value rights	2,080	—
Lease obligations, current	539	610
Deferred revenue	300	442
Convertible term loan	—	14,906
Total current liabilities	16,977	29,890
Lease obligations	2,622	52
Contingent value rights	440	—
Deferred tax liability	576	—
Total liabilities	20,615	29,942
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; authorized, 10,000,000 shares at December 31, 2020 and 2019; no shares issued or outstanding at December 31, 2020 and 2019	—	—
Preferred stock, $0.00759446 par value; unlimited authorized at December 31, 2019; 103,611 zero seed preferred shares issued and outstanding at December 31, 2019, respectively	—	—
Preferred stock, $0.00759446 par value; unlimited authorized at December 31, 2019; 1,441,418 series A preferred shares issued and outstanding at December 31, 2019, respectively	—	—
Common Stock, $0.0001 par value; authorized 200,000,000 shares at December 31, 2020 and December 31, 2019; 9,100,117 and 4,128,441 shares issues and outstanding at December 31, 2020 and 2019	1	1
Additional paid-in capital	91,238	31,718
Accumulated other comprehensive loss	(1,077)	(1,634)
Accumulated deficit	(47,168)	(21,549)
Total stockholders' equity	42,994	8,536
Total liabilities and stockholders' equity	$ 63,609	$ 38,478

The accompanying notes are an integral part of these consolidated financial statements.

F-star Therapeutics Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, Except Share and Per Share Amounts)

	Year Ended December 31,	
	2020	2019
License revenue	$ 11,256	$ 28,321
Operating expenses:		
Research and development	14,128	31,386
General and administrative	19,513	15,280
Impairment on intangible assets	—	4,152
Total operating expenses	33,641	50,818
Loss from operations	(22,385)	(22,497)
Other non-operating (expense) income:		
Other (expense) income	(849)	197
Change in fair value of convertible debt	(2,386)	(1,450)
Loss before income taxes	(25,620)	(23,750)
Income tax benefit	1	737
Net loss	$ (25,619)	$ (23,013)
Net loss attributable to common stockholders	$ (25,619)	$ (23,013)
Basic and diluted adjusted net loss per common shares	$ (9.69)	$ (14.89)
Weighted-average number of common shares outstanding, basic and diluted	2,643,175	1,545,177
Other comprehensive loss:		
Net loss	$ (25,619)	$ (23,013)
Other comprehensive gain (loss):		
Foreign currency translation	557	(1,246)
Total comprehensive loss	$ (25,062)	$ (24,259)

The accompanying notes are an integral part of these consolidated financial statements .

F-star Therapeutics Inc.
Consolidated Statements of Stockholders' Equity (Deficit)
(In thousands, except share amounts)

	Seed preferred shares	Series A preferred shares	Shareholders' Equity (Deficit)					
			Common Shares		Capital in Excess of par Value	Accumulated Other Comprehensive Loss	Retained Earnings (Accumulated deficit)	Total Stockholders' Equity (Deficit)
	Number	Number	Number	Value				
Balance at January 1, 2019	—	—	**4,108,654**	**$ 1**	**$ —**	**$ (388)**	**$ 1,464**	**$ 1,077**
Issuance of shares for acquisition of GmbH	103,611	—	—	—	169	—	—	169
Issuance of shares for acquisition of GmbH	—	1,441,418	—	—	2,360	—	—	2,360
Issuance of shares for acquisition of Delta	—	—	—	—	14,823	—	—	14,823
Issuance of shares for acquisition of Beta	—	—	—	—	10,556	—	—	10,556
Issuance of shares for acquisition of GmbH	—	—	—	—	206	—	—	206
Issuance of shares for acquisition of Alpha	—	—	—	—	935	—	—	935
Issuance of common stock for services rendered	—	—	19,637	—	—	—	—	—
Issuance of common stock in connection with at-the-market offering	—	—	150	—	—	—	—	—
Equity adjustment from foreign currency translation	—	—	—	—	—	(1,246)	—	(1,246)
Share-based compensation	—	—	—	—	2,669	—	—	2,669
Net loss	—	—	—	—	—	—	(23,013)	(23,013)
Balance at December 31, 2019	103,611	1,441,418	4,128,441	1	31,718	(1,634)	(21,549)	8,536
Issuance of common stock for services rendered	—	—	15,636	—	—	—	—	—
Issuance of common stock in connection with	—	—		—	—	—	—	—
at-the-market offering, net of issuance costs	—	—	172,724	—	—	—	—	—
Issuance of common stock pursuant to vesting of restricted stock units	—	—	133,000	—	—	—	—	—
Purchase of fractional shares	—	—	(242)	—	—	—	—	—
Exchange of common stock in connection of the transaction, net of issuance costs	(103,611)	(1,441,418)	4,620,618	—	55,781	—	—	55,781
Issuance of ordinary shares for professional services	—	—	29,940	—	250	—	—	250
Equity adjustment from foreign currency translation	—	—	—	—	—	557	—	557
Net loss	—	—	—	—	—	—	(25,619)	(25,619)
Share-based compensation	—	—	—	—	3,489	—	—	3,489
Balance at December 31, 2020	**—**	**—**	**9,100,117**	**$ 1**	**$ 91,238**	**$ (1,077)**	**$ (47,168)**	**$ 42,994**

The accompanying notes are an integral part of these consolidated financial statements.

F-star Therapeutics Inc.
Consolidated Statements of Cash Flows
(In thousands)

	For the Year Ended December 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$(25,619)	$(23,013)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Share based compensation expense	3,489	2,669
Foreign currency loss	338	81
Loss on disposal of tangible fixed assets	7	14
Depreciation	1,144	844
Intangible asset impairment	—	4,152
Interest expense	1,002	197
Fair value adjustment of convertible term loan	2,386	1,450
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	621	322
Tax incentive receivable	6,944	(5,883)
Accounts payable	(2,847)	3,049
Accounts payable to related parties	—	(789)
Accrued expenses and other current liabilities	(2,890)	1,525
Deferred revenue	(149)	(6,350)
Operating lease liability	(652)	(379)
Net cash used in by operating activities	(16,226)	(22,111)
Cash flows from investing activities:		
Cash acquired with transaction	9,779	—
Cash acquired with subsidiaries*	—	5,499
Proceeds from sale of marketable securities	5,000	—
Purchase of intangible assets	(730)	(127)
Net cash provided by investing activities	14,049	5,372
Cash flows from financing activities:		
Proceeds from issuance of convertible notes	850	13,264
Proceeds from private placement	15,000	—
Net cash provided by financing activities	15,850	13,264
Net increase (decrease) in cash and cash equivalents	13,673	(3,475)
Effect of exchange rate changes on cash	(48)	180
Cash and cash equivalents at beginning of year	4,901	8,196
Cash and cash equivalents at end of year	$ 18,526	$ 4,901
Supplemental disclosure of cash flow information		
Cash paid for income taxes	$ 124	$ 249
Cash paid for amounts included in the measurement of operating lease	$ 662	$ 380
Supplemental disclosure of non-cash information		
Fair value of net assets acquired	$ 21,536	$ —

* Consideration for acquisition of subsidiaries was entirely in the form of issued shares. See note 5 for supplemental disclosure of assets and liabilities acquired with subsidiaries.

The accompanying notes are an integral part of these consolidated financial statements.

F-star Therapeutics Inc.
Notes to the Consolidated Financial Statements

1. Nature of the business

F-star Therapeutics Inc. (formerly Spring Bank Pharmaceuticals Inc.) is a clinical-stage biopharmaceutical company dedicated to developing next generation immunotherapies to transform the lives of patients with cancer. Our goal is to offer patients better and more durable benefits than currently available immuno-oncology treatments by developing medicines that seek to block tumor immune evasion. Through our proprietary tetravalent, bispecific natural antibody (mAb²™) format, our mission is to generate highly differentiated medicines with monoclonal antibody-like manufacturability, good safety and tolerability. With four distinct binding sites in a natural human antibody format, we believe our proprietary technology will overcome many of the challenges facing current immuno-oncology therapies, due to the strong pharmacology enabled by tetravalent bispecific binding.

Share Exchange Agreement

On November 20, 2020, F-star Therapeutics, Inc. (the "Company or F-star"), formerly known as Spring Bank Pharmaceuticals, Inc.("Spring Bank"), completed its business combination (the "Transaction") with F-star Therapeutics Limited ("F-star Ltd") in accordance with the terms of the Share Exchange Agreement, dated July 29, 2020 (the "Exchange Agreement"), by and among the Company, F-star Ltd and the holders of issued shares in the capital stock of F-star Ltd and the holders of convertible notes of F-star Ltd each as set forth therein (each a "Seller", and collectively with holders of F-star Ltd securities who subsequently became parties to the Exchange Agreement, the "Sellers"). Pursuant to the Exchange Agreement, each ordinary share of F-star Ltd outstanding immediately prior to the closing of the Transaction (the "Closing") was exchanged by the Seller that owns such F-star Ltd shares for such number of duly authorized, validly issued, fully paid and non-assessable shares of Company common stock as is equal to the exchange ratio formula determined pursuant to the Exchange Agreement (the "Exchange Ratio"), rounded to the nearest whole share of Company common stock (after aggregating all fractional shares of Company common stock issuable to such Seller). Also, on November 20, 2020, in connection with, and prior to completion of, the Transaction, Spring Bank effected a 1-for-4 reverse stock split of its common stock (the "Reverse Stock Split") and, following the completion of the Transaction, changed its name to "F-star Therapeutics, Inc." Following the completion of the Transaction, the business of F-star Ltd became the business conducted by Company, which is a clinical-stage immuno-oncology company focused on cancer treatment through its proprietary tetravalent bispecific antibody programs. Unless otherwise noted, all references to share amounts in this report reflect the reverse stock split.

Under the terms of the Exchange Agreement, at the Closing, Spring Bank issued an aggregate of 4,620,618 shares of its common stock to F-star Ltd stockholders, based on an exchange ratio of 0.1125 shares of the Company's common stock for each F-star Ltd ordinary share, stock option and RSU outstanding immediately prior to the Closing. The exchange ratio was determined through arms-length negotiations between Spring Bank and F-star Ltd pursuant to a formula set forth in the Exchange Agreement.

Pursuant to the Exchange Agreement, immediately prior to the Closing, certain investors in F-star Ltd purchased $15.0 million of F-star Ltd ordinary shares (the "Pre-Closing Financing"). These ordinary shares of F-star Ltd were then exchanged at the Closing for shares of the Company's common stock in the Transaction at the same exchange rate.

Pursuant to the Exchange Agreement, all outstanding options to purchase Spring Bank common stock were accelerated immediately prior to the Closing and each outstanding option with an exercise price greater than the closing price of the stock on the Closing Date was exercised in full and all other outstanding options to purchase Company common stock were cancelled effective as of the Closing Date.

Immediately following the Reverse Stock Split and the Closing, there were approximately 4,449,559 shares of Spring Bank common stock outstanding. Following the Closing, the F-star Ltd stockholders beneficially owned

approximately 53.7% of the combined Company's common stock and the existing stockholders of Spring Bank beneficially owned approximately 46.3% of the Company's common stock outstanding. Concurrently with the execution of the Exchange Agreement, certain officers and directors of Spring Bank and F-star Ltd and certain stockholders of F-star Ltd entered into lock-up agreements (the "Lock-up Agreements"), pursuant to which they agreed to certain restrictions on transfers of any shares of the Company's common stock for the 180-day period following the Closing, other than the shares of the Company's common stock received in exchange for ordinary shares of F-star Ltd subscribed for in the Pre-Closing Financing and pursuant to certain other limited exceptions.

In addition, at the Closing, Spring Bank, F-star Ltd, a representative of Spring Bank stockholders prior to the Closing, and Computershare Trust Company N.A., as the Rights Agent, entered into a STING Agonist Contingent Value Rights Agreement (the "STING Agonist CVR Agreement"). Pursuant to the Exchange Agreement and the STING Agonist CVR Agreement, each pre-Reverse Stock Split share of Company common stock held by stockholders as of the record date on November 19, 2020 immediately prior to the Closing received a dividend of one contingent value right ("STING Agonist CVR"), payable on a pre-Reverse Stock Split basis, entitling such holders to receive, in connection with certain transactions involving proprietary STimulator of INterferon Genes (STING) agonist compound designated as SB 11285 occurring on or prior to the STING Agonist CVR Expiration Date (as defined below) that result in aggregate Net Proceeds (as defined in the STING Agonist CVR Agreement) at least equal to the Target Payment Amount (as defined below): an aggregate amount equal to the greater of (i) 25% of the Net Proceeds received from all CVR Transactions (as defined in the STING Agonist CVR Agreement) and (ii) an aggregate amount equal to the product of $1.00 and the total number of shares of Company common stock outstanding as of such record date (not to exceed an aggregate amount of $18.0 million) (the "Target Payment Amount").

The CVR payment obligation expires on the later of 18 months following the Closing or the one-year anniversary of the date of the final database lock of the Company's current STING clinical trial (as defined in the STING Agonist CVR Agreement) (the "STING Agonist CVR Expiration Date"). The STING Agonist CVRs are not transferable, except in certain limited circumstances, are not certificated or evidenced by any instrument, do not accrue interest and are not registered with the Securities and Exchange Commission (the "SEC") or listed for trading on any exchange. Until the STING Agonist CVR Expiration Date, subject to certain exceptions, the Company is required to use commercially reasonable efforts to (a) complete the STING Trial and (b) pursue a CVR Transaction. Unless terminated earlier in accordance with its terms, the STING Agonist CVR Agreement became effective upon the Closing will continue in effect until the STING Agonist CVR Expiration Date the payment of all CVR payment amounts are paid pursuant to its terms.

At the Closing, Spring Bank, F-star Ltd, a representative of Spring Bank stockholders prior to the Closing, and Computershare Trust Company N.A., as the Rights Agent, also entered into a STING Antagonist Contingent Value Rights Agreement (the "STING Antagonist CVR Agreement"). Pursuant to the Exchange Agreement and the STING Antagonist CVR Agreement, each share of common stock held by stockholders as of a record date immediately prior to the Closing will receive a dividend of one contingent value right ("STING Antagonist CVR") entitling such holders to receive, in connection with the execution of a potential development agreement (the "Approved Development Agreement") and certain other transactions involving proprietary STING antagonist compound occurring on or prior to the STING Antagonist CVR Expiration Date (as defined below) equal to: 80% of all net proceeds (as defined in the STING Antagonist CVR Agreement) received by the Company after the Closing pursuant to (i) the Approved Development Agreement, if any, and (ii) all CVR Transactions (as defined in the STING Antagonist CVR Agreement) entered into prior to the STING Antagonist CVR Expiration Date (as defined below).

The CVR payment obligations expire on the seventh anniversary of the Closing (the "STING Antagonist CVR Expiration Date"). The STING Antagonist CVRs are not transferable, except in certain limited circumstances, are not certificated or evidenced by any instrument, do not accrue interest and are not registered with the SEC or listed for trading on any exchange. Until the STING Antagonist CVR Expiration Date, subject to certain exceptions, the Company is required to use commercially reasonable efforts to (a) consummate the Approved

Development Agreement to the extent not entered into prior to Closing, (b) to perform the terms of the Approved Development Agreement and (c) pursue CVR Transactions. Unless terminated earlier in accordance with its terms, the STING Antagonist CVR Agreement became effective upon the Closing and will continue in effect until the STING Antagonist CVR Expiration Date or all CVR payment amounts are paid pursuant to its terms.

The acquisition-date fair value of the contingent valuation rights liability represents the future payments that are contingent upon the achievement of sale or licencing for the product candidates. The fair value of the contingent consideration assumed of $2.5 million as of December 31, 2020 is based on the Company's probability-weighted discounted cash flow assessment that considers probability and timing of future payments. The fair value measurement is based on significant Level 3 unobservable inputs such as the probability of achieving a sale or licensing agreement, anticipated timelines and discount rate. Changes in the fair value of the liability will be recognized in the consolidated statement of operations and comprehensive loss until settlement.

At the Closing, all issued share options and restricted stock units granted by F-star Ltd under the F-star Therapeutics Limited 2019 Equity Incentive Plan were replaced by options ("Replacement Options") and awards ("Replacement RSUs"), on the same terms (including vesting), for Company common stock, based on the Exchange Ratio.

The Company's common stock, which was listed on the Nasdaq Capital Market, traded through the close of business on Friday, November 20, 2020 under the ticker symbol "SBPH" and continued trading on the Nasdaq Capital Market, on a post-Reverse Stock Split adjusted basis, under the ticker symbol "FSTX" beginning on Monday, November 23, 2020. Commencing on November 23, 2020, the Company's common stock was represented by a new CUSIP number, 30315R 107. After the Transaction, the Company had approximately $30 million in cash. The combined company is now headquartered out of F-star Ltd existing facilities in Cambridge, U.K. and office in Cambridge, MA.

The Transaction was accounted for as a business combination using the acquisition method of accounting under the provisions of Financial Accounting Standards Board, Accounting Standards Codification ("ASC 805"), Topic 805 "Business Combinations" ("ASC 805"). The Transaction was accounted for as a reverse acquisition with F-star Ltd being deemed the acquiring company for accounting purposes. Under ASC 805, F-star Ltd as the accounting acquirer, recorded the assets acquired and liabilities assumed of Spring Bank Pharmaceuticals, Inc in the Transaction at their fair values as of the acquisition date (Note 4).

F-star Ltd was determined to be the accounting acquirer based on an analysis of the criteria outlined in ASC 805 and the facts and circumstances specific to the Transaction, including the fact that immediately following the Transaction: (1) F-star Ltd shareholders owned the majority of the voting rights of the combined company; (2) F-star Ltd designated a majority (five of eight) of the initial members of the board of directors of the combined company; and (3) F-star Ltd senior management held the key positions in senior management of the combined company. As a result, upon consummation of the Transaction, the historical financial statements of F-star Ltd became the historical financial statements of the combined organization.

2019 reorganization

On May 7, 2019, F-star Ltd acquired 100% of the issued share capital of F-star Delta Ltd ("Delta"), F-star Beta Ltd ("Beta"), F-star Biotechnologische Forschungs-und Entwicklungsges.m.b.H. ("GmbH"), and F-star Alpha Ltd ("Alpha") (collectively, the "F-star Group Entities").

The shareholdings in the F-star Group Entities were transferred to F-star Ltd in consideration of the issue of new shares in F-star Ltd to the shareholders of Alpha, Beta, Delta and GmbH. The transactions were all enacted on May 7, 2019, in two steps:

1. The shareholders in Delta transferred their shares to F-star Ltd in consideration of receiving new shares in F-star Ltd (corporate reorganization).

2. The shareholders in Beta, GmbH and Alpha transferred their shares to F-star Ltd in consideration of receiving new shares in F-star Ltd (business combination and asset acquisition).

F-star Ltd, the legal acquirer of the F-star Group Entities, is an entity with no historical operations and was created solely for the purpose of effecting the corporate reorganization. Accordingly, it was not deemed substantive nor the accounting acquirer of the F-star Group Entities. The initial transaction was therefore accounted for as a reverse acquisition with Delta subsequently obtaining a controlling interest in GmbH and Beta, and a controlling interest in Alpha through asset acquisition. The effect of the reverse acquisition accounting is that the financial statements to the date of consolidation (May 7, 2019) reflect the operations, historical financial position and financial performance of Delta.

The primary reason for the 2019 reorganization was to bring the F-star Ltd entities under common ownership of a holding company to enable management to enact its financial strategy of listing the share capital of F-star Group Entities on a public exchange.

Risks and Uncertainties

The Company is subject to risks common to companies in the biotechnology industry, including but not limited to, risks of failure of preclinical studies and clinical trials, the need to obtain marketing approval for any drug product candidate that it may identify and develop, the need to successfully commercialize and gain market acceptance of its product candidates, dependence on key personnel and collaboration partners, protection of proprietary technology, compliance with government regulations, development by competitors of technological innovations, and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval prior to commercialization. Even if the Company's research and development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

The accompanying consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. Since inception, the Company has devoted substantially all of its efforts to business planning, research and development, clinical expenses, recruiting management and technical staff, and securing funding via collaborations. The Company has historically funded its operations with proceeds received from its collaboration arrangements, sale of equity capital and proceeds from sales of convertible notes. The Company had approximately $18.5 million in cash as of December 31, 2020. The Company expects to continue to generate operating losses in the foreseeable future, particularly as the Company advances its preclinical activities and clinical trials for its product candidates in development. The Company plans to seek additional funding through public equity, private equity, debt financing, collaboration partnerships, or other sources. There are no assurances, however, that the Company will be successful in these endeavors.

If the Company is unable to obtain funding, the Company could be forced to delay, reduce, or eliminate its research and development programs, or reduce product candidate expansion, which could adversely affect its business prospects. Although management continues to pursue its funding plans, there is no assurance that the Company will be successful in obtaining sufficient funding to fund continuing operations on terms acceptable to the Company , if at all. Accordingly, the Company has concluded that substantial doubt exists about the Company's ability to continue as a going concern for a period of at least twelve months from the date of the financial statements.

Impact of Covid-19 on our Business

In March 2020, the World Health Organization declared the novel strain of coronavirus (COVID-19) a pandemic and recommended containment and mitigation measures worldwide. The COVID-19 pandemic has been

evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures.

Management continues to closely monitor the impact of the COVID-19 pandemic on all aspects of the business, including how it will impact operations and the operations of customers, vendors, and business partners. Management took action in April 2020 to temporarily furlough some of its workforce and took advantage of the UK Government Coronavirus Job Retention Scheme (CJRS) that provided funding to businesses with furloughed staff. The grant funding available covered 80% of furloughed employees' wages plus employer National Insurance and pension contributions up to a maximum of £2,500 per month per furloughed employee. The onset of the global pandemic resulted in a three to six month delay in the operationalization of the Company's clinical trials for FS118, FS120, FS222 and SB 11285. The extent to which COVID-19 impacts the future business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence at this time, such as the continued duration of the outbreak, new information that may emerge concerning the severity or other strains of COVID-19 or the effectiveness of actions to contain COVID-19 or treat its impact, among others. If the Company or any of the third parties with which it engages, however, were to experience shutdowns or other business disruptions, the ability to conduct business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on business, results of operations and financial condition. The estimates of the impact on the Company's business may change based on new information that may emerge concerning COVID-19 and the actions to contain it or treat its impact and the economic impact on local, regional, national, and international markets.

Management have not identified any triggering events which would result in any significant impairment losses in the carrying values of assets as a result of the pandemic and are not aware of any specific related event or circumstance that would require management to revise estimates reflected in these consolidated financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's financial statements have been prepared in conformity with generally accepted accounting principles in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

The accompanying consolidated financial statements include the accounts of F-star Therapeutics Inc. and its wholly owned subsidiaries:

F-star Therapeutics Limited, (F-star Ltd); F-star Delta Limited, ("Delta"); F-star Beta Limited, ("Beta"); F-star Biotechnology Limited, ("Biotechnology"); F-star Alpha Limited, ("Alpha"); f-star Biotechnologische Forschungs-und Entwicklungsges.m.b.H, ("GmbH"); F-star Therapeutics LLC; Sperovie Biosciences, Inc.; SBP Securities Corporation and SBP International Limited.

All intercompany balances and transactions between the consolidated companies have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the

reporting years. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the fair value of the assets and liabilities acquired in the transaction between Spring Bank and F-star Ltd, the acquisition of Alpha, Beta, Delta and GmbH as part of the 2019 reorganization, fair value of the convertible loan containing embedded derivatives, the accrual for research and development expenses, revenue recognition, fair values of acquired intangible assets and impairment review of those assets, share based compensation expense, and income taxes. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. Estimates are periodically reviewed in light of reasonable changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates or assumptions.

Foreign currency and currency translation

The functional currency is the currency of the primary economic environment in which an entity's operations are conducted. The Company and its subsidiaries operate mainly in the United Kingdom, United States and Austria.

The Company's reporting currency is the U.S dollar. The Company translates the assets and liabilities of its subsidiaries into U.S. dollar at the exchange rate in effect on the balance sheet date. Revenues and expenses are translated at the average exchange rate in effect during each monthly period. Unrealized translation gains and losses are recorded as a cumulative translation adjustment, which is included in the consolidated statements of shareholders' equity as a component of accumulated other comprehensive (loss)income. Translation differences resulting from the conversion from functional currency to reporting currency are included as part of the cumulative foreign currency translation adjustment, which is reported as a component of shareholders' equity under accumulated other comprehensive loss.

Monetary assets and liabilities denominated in currencies other than the functional currency are remeasured into the functional currency at rates of exchange prevailing at the balance sheet dates. Non-monetary assets and liabilities denominated in foreign currencies are remeasured into the functional currency at the exchange rates prevailing at the date of the transaction. Exchange gains or losses arising from foreign currency transactions are included in the determination of net loss for the respective periods.

Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the local currency are included in other (expense) income in the consolidated statements of operations and comprehensive loss as incurred. The Company recorded a foreign exchange loss of $0.4 million and a gain of $ 0.3 million included in other (expense) income in the consolidated statement of operations and comprehensive loss for the years ended December 31, 2020, and 2019, respectively.

Emerging Growth Company

Section 102(b)(1) of the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that an emerging growth company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has irrevocably elected to "opt out" of this provision and, as a result, the Company will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

Concentrations of credit risk and of significant suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains its cash and cash equivalents in financial institutions in

amounts that could exceed government-insured limits. The Company does not believe it is subject to additional credit risks beyond those normally associated with commercial banking relationships.

The Company is dependent on third-party manufacturers to supply products for research and development activities in its programs. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply its requirements for supplies and raw materials related to these programs. These programs could be adversely affected by a significant interruption in these manufacturing services or the availability of raw materials.

Cash and cash equivalents

The Company considers all highly liquid investments with original maturities of three months or less at date of purchase to be cash equivalents. The Company had no cash equivalents on December 31, 2020, and 2019.

Property, plant and equipment

Property, plant and equipment are stated at cost, less accumulated depreciation . Depreciation expense is recognized using the straight-line method over the estimated useful lives of the respective assets as follows:

	Estimated Useful Economic Life
Leasehold property improvements, right of use assets	Lesser of lease term or useful life
Laboratory equipment	5 years
Furniture and office equipment	3 years

Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated in accordance with the above guidelines once placed into service. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in loss from operations. As of December 31, 2020, and 2019, there have been no significant asset retirements to date. Expenditures for repairs and maintenance that do not improve or extend the lives of the respective assets are charged to expense as incurred.

Impairment of long-lived assets

Long-lived assets consist of property, plant and equipment, goodwill, and intangible assets. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. An impairment loss would be recognized as a loss from operations when estimated undiscounted future cash flows expected to result from the use of an asset group or the estimated return on investment are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flow or return on investment calculations. The Company recorded an impairment loss on long-lived assets of $4.2 million during the year ended December 31, 2019.

Business Combinations and Goodwill

Business combinations are accounted for in accordance with ASC Topic 805 “Business Combinations”. The total purchase price of an acquisition is allocated to the underlying identifiable net assets, based on their respective estimated fair values as of the acquisition date. Determining the fair value of assets acquired and liabilities assumed requires management’s judgment and often involves the use of significant estimates and assumptions,

including assumptions with respect to future cash inflows and outflows, probabilities of success, discount rates, and asset lives, among other items. Assets acquired and liabilities assumed are recorded at their estimated fair values. The excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill. Goodwill is tested for impairment at the reporting unit level annually in the fourth quarter, or more frequently when events or changes in circumstances indicate that the asset might be impaired. Examples of such events or circumstances include, but are not limited to, a significant adverse change in legal or business climate, an adverse regulatory action or unanticipated competition. The Company has determined that it operates in a single operating segment and has a single reporting unit. To perform its quantitative test, the Company compares the fair value of the reporting unit to its carrying value. If the fair value of the reporting unit exceeds the carrying value of its net assets, goodwill is not impaired, and no further testing is required. If the fair value of the reporting unit is less than the carrying value, the Company measures the amount of impairment loss, if any, as the excess of the carrying value over the fair value of the reporting unit. Required annual testing of goodwill for impairment was completed as of December 31, 20 20 and determined that goodwill is not impaired.

Contingent value rights

The acquisition-date fair value of the contingent valuation rights liability represents the future payments that are contingent upon the achievement of sale or licencing for the STING product candidates. The fair value of the contingent value rights is based on the Company's probability-weighted discounted cash flow assessment that considers probability and timing of future payments. The fair value measurement is based on significant Level 3 unobservable inputs such as the probability of achieving a sale or licensing agreement, anticipated timelines, and discount rate. Changes in the fair value of the liability will be recognized in the consolidated statement of operations and comprehensive loss until settlement.

Acquired In-Process Research and Development (IPR&D)

Acquired IPR&D represents the fair value assigned to research and development assets that the Company acquires and have not been completed at the acquisition date. The fair value of IPR&D acquired in a business combination is recorded on the consolidated balance sheets at the acquisition-date fair value and is determined by estimating the costs to develop the technology into commercially viable products, estimating the resulting revenue from the projects, and discounting the projected net cash flows to present value. IPR&D is not amortized, but rather is reviewed for impairment on an annual basis or more frequently if indicators of impairment are present, until the project is completed, abandoned or transferred to a third party. The projected discounted cash flow models used to estimate the fair value of partnered assets and cost approach model used to estimate proprietary assets as part of the Company's IPR&D reflect significant assumptions regarding the estimates a market participant would make in order to evaluate a drug development asset, including the following:

- Estimates of obsolescence of development expenditure;
- Probability of successfully completing clinical trials and obtaining regulatory approval;
- Estimates of future cash flows from potential milestone payments and royalties related to out-licensed product sales; and
- A discount rate reflecting the Company's weighted average cost of capital and specific risk inherent in the underlying assets.

Once brought into use, intangible assets are amortized over their estimated useful economic lives, which for acquired IPR&D assets is over the remaining life of the relevant patents.

Fair value measurements of financial instruments

The Company's financial instruments consist of cash, accounts payable, CVR and liability classified warrants. The carrying amounts of cash and accounts payable approximate their fair value due to the short-term nature of those financial instruments. The fair value of CVR and the liability classified warrants are remeasured to fair value each reporting period.

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Accounting Standards Codification ("ASC") Topic 820, Fair Value Measurement ("ASC 820"), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances.

ASC 820 identifies fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tier fair value hierarchy that distinguishes between the following:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 — Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The carrying amounts reflected in the consolidated balance sheets for cash and cash equivalents, and other current assets, research and development incentives receivable, accounts payable and accrued liabilities and other current liabilities approximate their fair values, due to their short-term nature.

Segment and geographic information

Operating segments are defined as components of a business for which separate discrete financial information is available for evaluation by the chief operating decision maker in deciding how to allocate resources and assess performance. The Company and its chief operating decision maker, the Company's Chief Executive Officer, view the Company's operations and manage its business as a single operating segment. The Company operates in three geographic areas: the United Kingdom, United States and Austria.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use ("ROU") assets, other current liabilities, and operating lease liabilities in the Company's consolidated balance sheets. The Company has not entered any financing leases.

ROU assets represent the Company's right to use and control an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The ROU asset also includes lease payments made before the lease commencement date and excludes any lease incentives. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option.

The components of a lease shall be split into three categories, if applicable: lease components (e.g., land, building, etc.), non-lease components (e.g., common area maintenance, maintenance, consumables, etc.), and non-components (e.g., property taxes, insurance, etc.). The fixed and in-substance fixed contract consideration (including any related to non-components) must then be allocated based on fair values to the lease components and non-lease components. The Company's facilities operating leases may have lease and non-lease components to which the Company has elected to apply a practical expedient to account for each lease component and related non-lease component as one single component. The lease component results in a right-of-use asset being recorded on the consolidated balance sheets. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

License and collaboration arrangements and revenue recognition

The Company's revenues are generated primarily through license and collaboration agreements with pharmaceutical and biotechnology companies. The terms of these arrangements may include (i) the grant of intellectual property rights (IP licenses) to therapeutic drug candidates against specified targets, developed using the Company's proprietary mAb^2 bispecific antibody platform, (ii) performing research and development services to optimize drug candidates, and (iii) the grant of options to obtain additional research and development services or licenses for additional targets, or to optimize product candidates, upon the payment of option fees.

The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, upfront license fees; payments for research and development services; fees upon the exercise of options to obtain additional services or licenses; payments based upon the achievement of defined collaboration objectives; future regulatory and sales-based milestone payments; and royalties on net sales of future products.

The Company has adopted Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("ASC") Topic 606—Revenue from Contracts with Customers ("ASC 606"). This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. To date, the Company has entered into License and Collaboration Agreements with Denali Therapeutics, Inc., and Ares Trading S.A. (an affiliate of Merck KGaA, Darmstadt, Germany) which were determined to be within the scope of ASC 606.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. In determining the appropriate amount of revenue to be recognized under ASC 606, the Company performs the following steps:

(i) identify the promised goods or services in the contract;

(ii) determine whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;

(iii) measurement of the transaction price, including the constraint on variable consideration;

(iv) allocation of the transaction price to the performance obligations; and

(v) recognition of revenue when (or as) the Company satisfies each performance obligation.

As part of the accounting for these arrangements, the Company must make significant judgments, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each performance obligation.

Once a contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within the contract and determines those that are performance obligations. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. The Company assesses if these options provide a material right to the customer and if so, they are considered performance obligations.

Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer. The promised goods or services in the Company's contracts with customers primarily consist of license rights to the Company's intellectual property for research and development, research and development services, options to acquire additional research and development services, and options to obtain additional licenses, such as a commercialization license for a potential product candidate. Promised goods or services are considered distinct when:

(i) the customer can benefit from the good or service on its own or together with other readily available resources; and

(ii) the promised good or service is separately identifiable from other promises in the contract.

In assessing whether promised goods or services are distinct, the Company considers factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on their own and whether the required expertise is readily available. In addition, the Company considers whether the collaboration partner can benefit from a promise for its intended purpose without the receipt of the remaining promises, whether the value of the promise is dependent on the unsatisfied promises, whether there are other vendors that could provide the remaining promises, and whether it is separately identifiable from the remaining promises. The Company estimates the transaction price based on the amount of consideration the Company expects to receive for transferring the promised goods or services in the contract. The consideration may include both fixed consideration and variable consideration. At the inception of each arrangement that includes variable consideration, the Company evaluates the amount of the potential payments and the likelihood that the payments will be received. The Company utilizes either the most likely amount method or expected value method to estimate variable consideration to include in the transaction price based on which method better predicts the amount of consideration expected to be received. The amount included in the transaction price is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

After the transaction price is determined it is allocated to the identified performance obligations based on the estimated standalone selling price. The Company must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. The Company utilizes key assumptions to determine the standalone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction, probabilities of technical and regulatory success and the estimated costs. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amounts the Company would expect to receive for each performance obligation.

The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied at a point in time or over time, and if over time based on the use of an input method.

The Company accounts for contract modifications as a separate contract if both of the following conditions are met:

(i) the scope of the contract increases because of the addition of promised goods or services that are distinct; and

(ii) the price of the contract increases by an amount of consideration that reflects standalone selling prices of the additional promised goods or services and any appropriate adjustments to that price to reflect the circumstances of the particular contract.

If a contract modification is deemed to not be a separate contract, then the transaction price is updated and allocated to the remaining performance obligations (both from the existing contract and the modification). Previously recognized revenue for goods and services that are not distinct from the modified goods or services is adjusted based upon an updated measure of progress for the partially satisfied performance obligations.

If a contract modification is deemed to be a separate contract, any revenue recognized under the original contract is not retrospectively adjusted and any performance obligations remaining under the original contract continue to be recognized under the terms of that contract.

The Company's collaboration revenue arrangements include the following:

Up-front License Fees: If a license is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from nonrefundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone payments: The Company's collaboration agreements may include development and regulatory milestones. The Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjusts the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenue and net loss in the period of adjustment.

Customer Options: The Company evaluates the customer options to obtain additional items (i.e., additional license rights) for material rights, or options to acquire additional goods or services for free or at a discount. Optional future services that reflect their standalone selling prices do not provide the customer with a material right and, therefore, are not considered performance obligations and are accounted for as separate contracts. If optional future services include a material right, they are accounted for as performance obligations. The Company determines an estimated standalone selling price of any material rights for the purpose of allocating the transaction price. The Company considers factors such as the identified discount and the probability that the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until, at the earliest, the option is exercised or expires.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on a level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company will

recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any revenue related to sales-based royalties or milestone payments based on the level of sales.

Research and Development Services: The promises under the Company's collaboration agreements may include research and development services to be performed by the Company on behalf of the partner. Payments or reimbursements resulting from the Company's research and development efforts are recognized as the services are performed and presented on a gross basis because the Company is the principal for such efforts.

Research and development costs

Research and development costs are expensed as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including salaries, share-based compensation and benefits, facilities costs and laboratory supplies, depreciation, amortization and impairment expense, manufacturing expenses and external costs of outside vendors engaged to conduct preclinical development activities and clinical trials as well as the cost of licensing technology. Typically, upfront payments and milestone payments made for the licensing of technology are expensed as research and development in the period in which they are incurred, except for payments relating for intellectual property rights with future alternative use which will be expensed when the intellectual property is in use. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

Research contract costs and accruals

The Company has entered into various research and development contracts with companies both inside and outside of the United States. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Research and development incentives and receivable

The Company, through its subsidiaries in the United Kingdom, receives reimbursements of certain research and development expenditures as part of a United Kingdom government's research and development tax reliefs program. Under the program, the Company is able to surrender trading losses that arise from qualifying research and development expenses incurred in the United Kingdom for a tax credit of up to 14.5% of the surrender able losses. Management has assessed the Company's research and development activities and expenditures to determine which activities and expenditures are likely to be eligible under the research and development incentive program described above. At each period end, management estimates the reimbursement available to the Company based on available information at the time.

The Company recognizes income from the research and development incentives when the relevant expenditure has been incurred, the associated conditions have been satisfied and there is reasonable assurance that the reimbursement will be received. The Company records these research and development incentives as a reduction to research and development expenses in the consolidated statements of operations and comprehensive loss, as the research and development tax credits are not dependent on the Company generating future taxable income, the Company's ongoing tax status, or tax position. The research and development incentives receivable represent an amount due in connection with the above program. The Company recorded a reduction to research and development expense of $3.3 million and $6.6 million for the year ended December 31, 2020 and 2019, respectively.

Patent costs

All patent-related costs incurred in connection with preparing, filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses in the consolidated statements of operations and comprehensive loss.

Warrants

The Company accounts for freestanding warrants within stockholder's equity or as liabilities based on the characteristics and provisions of each instrument. The Company evaluates outstanding warrants in accordance with Accounting Standards Codification ("ASC") 480, *Distinguishing Liabilities from Equity*, and ASC 815, *Derivatives and Hedging*. If none of the criteria in the evaluation in these standards are met, the warrants are classified as a component of stockholders' equity and initially recorded at their grant date fair value without subsequent remeasurement. Warrants that meet the criteria are classified as liabilities and remeasured to their fair value at the end of each reporting period.

Share-based compensation

The Company accounts for share-based compensation in accordance with ASC 718, 'Compensation – Stock Compensation"("ASC 718"). ASC 718 requires companies to estimate the fair value of equity-based payment awards on the date of grant. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service period in the Company's consolidated statements of operations and comprehensive loss.

The Company records the expense for option awards using a graded vesting method. The Company accounts for forfeitures as they occur. For share-based awards granted to non-employee consultants, the measurement date for non-employee awards is the date of grant. The compensation expense is then recognized over the requisite service period, which is the vesting period of the respective award.

The Company reviews stock award modifications when there is an exchange of original award for a new award. The Company calculates for the incremental fair value based on the difference between the fair value of the modified award and the fair value of the original award immediately before it was modified. The Company immediately recognizes the incremental value as compensation cost for vested awards and recognizes, on a prospective basis over the remaining requisite service period, the sum of the incremental compensation cost and any remaining unrecognized compensation cost for the original award on the modification date.

The fair value of stock options ("options") on the grant date is estimated using the Black-Scholes option-pricing model using the single-option approach. The Black-Scholes option pricing model requires the use of highly subjective and complex assumptions, including the option's expected term and the price volatility of the underlying stock, to determine the fair value of the award.

Historically given the absence of an active market for the ordinary shares of F-star Ltd, the board of directors determined the estimated fair value of the Company's equity instruments based on input from management, which utilized the most recently available independent third-party valuation, and considering a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector. Each valuation methodology includes estimates and assumptions that require judgment. These estimates and assumptions include a number of objective and subjective factors in determining the value of F-star Ltd ordinary shares at each grant date. The expected volatility for F star Ltd was calculated based on reported volatility data for a representative group of publicly traded companies for which historical information was available. The historical volatility is calculated based on a period of time commensurate with the assumption used for the expected term. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant

commensurate with the expected term assumption. F-star Ltd used the simplified method, under which the expected term is presumed to be the midpoint between the vesting date and the end of the contractual term. F-star Ltd utilized this method due to the lack of historical exercise data and the plain nature of its share-based awards.

The Company uses the remaining contractual term for the expected life of non-employee awards. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends.

The Company classifies share-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Comprehensive loss

Comprehensive loss includes net loss as well as other changes in shareholders' equity (deficit) that result from transactions and economic events other than those with shareholders. The Company records unrealized gains and losses related to foreign currency translation as a component of other comprehensive loss in the consolidated statements of operations and comprehensive loss.

Contingencies

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, penalties and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential loss range is probable and reasonably estimable under the provisions of the authoritative guidelines that address accounting for contingencies. The Company expenses costs as incurred in relation to such legal proceedings as general and administrative expense within the consolidated statements of operations and comprehensive loss.

Income taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that will more likely than not be realized upon ultimate settlement. Any provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Research and development tax credits received in the U.K. are recorded as a reduction to research and development expenses. The U.K. research and development tax credit is payable to the Company after

surrendering tax losses and is not dependent on current or future taxable income. As a result, it is not reflected as part of the income tax provision. If, in the future, any U.K. research and development tax credits generated are utilized to offset a corporate income tax liability in the U.K., that portion would be recorded as a benefit within the income tax provision and any refundable portion not dependent on taxable income would continue to be recorded as a reduction to research and development expenses.

Net loss per share

The Company computes net (loss) income per share in accordance with ASC Topic 260, "Earnings Per Share"("ASC 260") and related guidance, which requires two calculations of net (loss) income attributable to the Company's shareholders per share to be disclosed: basic and diluted. Convertible preferred shares are participating securities and are included in the calculation of basic and diluted net (loss) income per share using the two-class method. In periods where the Company reports net losses, such losses are not allocated to the convertible preferred shares for the computation of basic or diluted net (loss) income.

Diluted net (loss) income per share is the same as basic net (loss) income per share for the periods in which the Company had a net loss because the inclusion of outstanding common stock equivalents would be anti-dilutive.

Recently adopted accounting pronouncements

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement (ASU 2018-13), which modifies the disclosure requirements on fair value measurements with respect to Level 3 rollforwards, timing of liquidation of investments in certain entities that calculate net asset value, and measurement uncertainty. This standard became effective for the Company on January 1, 2020. The adoption of this standard did not have a material impact on our consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). ASU 2016-13 changes how companies account for credit losses for most financial assets and certain other instruments. For trade receivables, loans and held-to-maturity debt securities, companies are required to recognize an allowance for credit losses rather than reducing the carrying value of the asset. This standard became effective for the Company on January 1, 2020. The adoption of this standard did not have a material impact on our consolidated financial statements.

In November 2018, the FASB issued ASU No. 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606. This standard makes targeted improvements for collaborative arrangements as follows:

- Clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606, Revenue from Contracts with Customers, when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in ASC 606 should be applied, including recognition, measurement, presentation and disclosure requirements:
- Adds unit-of-account guidance to ASC 808, Collaborative Arrangements, to align with the guidance in ASC 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of ASC 606; and
- Precludes a company from presenting transactions with collaborative arrangement participants that are not directly related to sales to third parties with revenue recognized under ASC 606 if the collaborative arrangement participant is not a customer.

This standard became effective for the Company on January 1, 2020. The adoption of this standard did not have a material impact on our consolidated financial statements.

Recently issued accounting pronouncements

In December 2019, the FASB issued ASU No. 2019-12, "Income Taxes—Simplifying the Accounting for Income Taxes." The ASU simplifies the accounting for income taxes by removing certain exceptions to the general principles as well as clarifying and amending existing guidance to improve consistent application. The amendments to this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. Depending on the amendment, adoption may be applied on the retrospective, modified retrospective or prospective basis. The Company is currently evaluating the impact to the consolidated financial statements.

3. Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The accompanying financial statements do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if the Company is unable to continue as a going concern. The Company expects its costs and expenses to increase as it continues to develop its product candidates and progress its current clinical programs and cost associated with being a public company.

Pursuant to the requirements of Accounting Standard Codification (ASC) 205-40, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date of these financial statements, and (1) is probable that the plan will be effectively implemented within one year after the date the financial statements are issued, and (2) it is probable that the plan, when implemented, will mitigate the relevant condition or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date the financials are issued. Certain elements of the Company's operating plan to alleviate the conditions that raise substantial doubt are outside of the Company's control and cannot be included in management's evaluation under the requirements of Accounting Standard Codification (ASC) 205-40.

The Company has incurred significant losses and has an accumulated deficit of $ 47.2 million as of December 31, 2020. F-star expects to incur substantial losses in the foreseeable future as it conducts and expands its research and development activities. As of March 30, 2021, the date of issuance of the consolidated financial statements, the Company's current cash deposits will not be sufficient to fund its current operating plan and planned capital expenditures for at least the next 12 months. These conditions give rise to a substantial doubt over the Company's ability to continue as a going concern.

The Company intends to seek additional funding through public equity, private equity, debt financing, collaboration partnerships, or other sources. There are no assurances, however, that the Company will be successful in raising additional working capital, or if it is able to raise additional working capital, it may be unable to do so on commercially favorable terms. The Company's failure to raise capital or enter into other such arrangements if and when needed would have a negative impact on its business, results of operations and financial condition and its ability to develop its product candidates.

4. Business Combination

As described in Note 1 above, on November 20, 2020, F-star Ltd completed its business combination with Spring Bank. For accounting purposes, the purchase price was based on (i) the fair value of Spring Bank common stock as of the Transaction date of $21.5 million which was determined based on the number of shares of common stock in connection with the Transaction, (ii) the portion of the fair value attributable to in the money fully and partially vested stock options and warrants.

Under the acquisition method of accounting, the total purchase price is allocated to the acquired tangible and intangible assets and assumed liabilities based on their fair values as of the acquisition date. Any excess purchase price over the fair value of assets acquired and liabilities assumed is allocated to goodwill. Acquired in-process research and development assets will be classified as indefinite-lived intangible assets and will be amortized over their estimated useful economic lives when put into use. The fair values of acquired in-process research and development assets were calculated using an income approach based on the expected future cash flows associated with the respective asset using an estimated discount rate of 14%. In addition, on the date of the Transaction there were 73,337 outstanding equity classified warrants with a fair value of $0.2 million and 408,444 outstanding liability classified warrants with a fair value of $ 0.2 million.

Goodwill is allocated to one reporting unit. The goodwill was primarily attributable to the access F-star Ltd gained to the Nasdaq public listing. The Company determined that the underlying goodwill and intangible assets are not deductible for tax purposes.

For the year ended December 31, 2020, the Company incurred acquisition-related expenses of approximately $ 4.2 million which are included in general and administrative expenses. The purchase price is allocated to the fair value of assets and liabilities acquired as follows (in thousands, except common shares and fair value per share):

Number of full common shares	4,449,559
Multiplied by fair value per share of common stock	$ 4.84
Purchase price	$ 21,536
Cash and cash equivalents	$ 9,779
Marketable securities	5,000
Prepaid expenses and other assets	935
Operating lease right of use asset	2,784
Intangible assets	4,720
Goodwill	10,451
Accounts payable, accrued expenses and other liabilities	(5,453)
Contingent value rights	(2,520)
Liability and equity based warrants	(422)
Deferred tax liability	(576)
Operating lease liability	(3,162)
Fair value of net assets acquired	$ 21,536

A liability was recognized for the contingent value rights assumed by the Transaction. The fair value estimate for the contingent value rights was estimated at $2.5 million and is based on the probability weighted achieved over the estimated period. Any change in the fair value of the contingent value rights to the acquisition date, including changes from events after the acquisition date, such as changes in our estimate will be recognized in earnings in the period the estimated fair value changes. The company's estimated range of possible outcomes were up to $26.0 million. A change in fair value of the contingent value rights could have a material effect on the statement of operations and financial position in the period of the change in estimate.

The results of this acquisition were included in the Company's consolidated statement of operations and comprehensive loss beginning on November 20, 2020.

The Company's consolidated net loss for the year ended December 31, 2020, includes a loss of $ 1.7 million for Spring Bank operations since the Transaction date.

The unaudited pro forma financial information presents the combined results of operations as if the Transaction had occurred on January 1, 2019. The unaudited pro forma financial information is not necessarily indicative of

what the consolidated results of operations would have been had the Transaction occurred at the beginning of each year. In addition, the unaudited pro forma financial information does not attempt to project the future results of operations of the combined company. On a pro forma basis, the combined companies would have been a net loss of $47.1 million and $49.6 million for the year ended December 31, 2020 and 2019, respectively. The unaudited pro forma net losses for December 31, 2020 and 2019, respectively, gives effect to the exclusion of interest expense relating to the convertible debt and the change of the fair value relating the convertible debt.

5. 2019 Corporate Reorganization

On May 7, 2019, F-star Ltd completed a corporate reorganization pursuant to which F-star Ltd became the direct holding company of each of Alpha, Beta, Delta, and GmbH and the indirect holding company of each of F-star Biotechnology Limited ("Biotech"), and F-star Therapeutics LLC ("LLC") collectively, the "F-star Group Entities". Prior to the transactions described below, all F-star Group entities were deemed not to be under common control but were deemed to be related parties due to common directorships.

Exchange of Delta Shares for F-star Ltd Shares **(the 'Delta Share Exchange')**

All shareholders of Delta exchanged each of the shares held by them in Delta for the same class and number of newly issued shares of F-star Ltd and, as a result, Delta became a wholly owned subsidiary of F-star Ltd. The number of shares issued was 9,053,538 at a ratio of 1:1. This was accounted for as Delta obtaining a 100% controlling interest in F-star Ltd using reverse acquisition accounting principles. The primary reason for this business combination was to bring the F-star Group entities under direct common ownership to enact its financial strategy of listing the share capital of F-star Ltd on a public exchange.

F-star Ltd, the legal acquirer of Delta and the other F-star Group Entities (see below), is an entity with no historical operations and was created solely for the purpose of effecting the corporate reorganization. Accordingly, for accounting purposes, F-star Ltd was not deemed substantive nor the accounting acquirer of the F-star Group Entities. The effect of using reverse acquisition accounting is that the historical (prior to the date of acquisition) financial statements of F-star Ltd reflect the operations and historical financial position and financial performance of legal subsidiary Delta (the accounting acquirer).

Exchange of GmbH, Beta and Alpha Shares for F-star Ltd Shares (business combination and asset acquisition)

Effective as of the date of and subsequent to the Delta Share Exchange, all shareholders of each of Alpha, Beta and GmbH exchanged each of the shares held in Alpha, Beta and GmbH for newly issued shares in F-star Ltd. As a result, Alpha, Beta and GmbH became wholly owned subsidiaries of F-star Ltd. Holders of options to purchase shares of Alpha, Beta and GmbH swapped their existing options for new options to purchase shares of F-star Ltd.

GmbH and Beta were deemed to meet the definition of a business in accordance ASC 805 and therefore the acquisitions were accounted for as business combinations, while the acquisition of a controlling interest in Alpha was accounted for as an asset acquisition. No other assets, including cash, were transferred or liabilities assumed as consideration for the corporate reorganization. The acquisition of F-star Ltd by Delta did not contribute any revenue and contributed a loss of $4.8 million to the Company's results in 2019.

Beta

As consideration paid for the acquisition of Beta, F-star Ltd issued 6,446,843 shares at a fair value of $5.6 million on the acquisition date.

The assets and liabilities recognized as a result of the acquisition of Beta are as follows (in thousands):

Cash and cash equivalents	$ 1,205
Other current assets	5,475
In-process research and development	15,958
Goodwill	2,293
Current liabilities	(19,376)
	$ 5,555

The acquisition of Beta by Delta did not contribute any revenue and contributed a loss of $ 12.4 million during 2019 for the period of May 7, 2019 through December 31, 2019.

The following unaudited supplemental pro forma information summarizes the results of operations of Beta as if the acquisition had occurred on January 1, 2018:

	Period from January 1 to May 6, 2019
Revenue	$ —
Net loss	(5,549)

The goodwill is attributable to the contracted access to an organized workforce and will not be deductible for tax purposes. The in-process research and development intangible assets represent the acquisition-date fair value of three development programs acquired from Beta, which the Company refers to as the FS120, FS222 and FS21. FS120 and FS222 are Beta proprietary assets and FS21 is partnered. The fair value of the IPR&D intangible assets was based on assumptions that market participants would use in pricing the assets, given that they are early stage, based on the most advantageous market for the assets assuming highest and best use.

The fair value of assets not subject to partnering agreements (FS120 and FS222) was determined using a cost approach, which utilized net amount invested with a return on investment commensurate with the achievement of certain value inflection events, benchmarked against publicly available information from comparable companies.

For the partnered asset (FS21) the calculations include cash flow projections based on financial budgets approved by management covering a three-year year. Cash flows beyond the three-year period are forecasted using published transition probabilities for development of biological therapeutic molecules, expected clinical study design based upon the clinical development strategy for the pipeline assets and industry analyst sales and gross margin projections for similar molecules in the same target indications.

These IPR&D intangible assets are not amortized, but rather are reviewed for impairment on an annual basis or more frequently if indicators of impairment are present, until the project is completed, abandoned or transferred to a third party.

The intangible assets acquired with Beta are summarized in the table below (in thousands):

	FV	Description
FS21	$ 4,426	Contracted future cash flows relating to a drug candidate that has been licensed to a collaboration partner
FS120	6,359	Internally developed drug candidate, for which Beta holds the IP rights
FS222	5,173	Internally developed drug candidate, for which Beta holds the IP rights
	$15,958	

GmbH Group

As consideration paid for the acquisition of GmbH, F-star Ltd issued 1,441,418 of series A preferred shares, 103,611 seed preferred shares and 125,715 of ordinary shares at a fair value of $ 9.4 million on the date of acquisition.

The assets and liabilities recognized as a result of the acquisition of GmbH Group are as follows (in thousands):

Cash	$ 952
Other current assets	18,211
Property and equipment	1,965
Right of use assets	975
In process research and development	1,436
Equity investment	56
Current liabilities	(15,751)
Other non-current liabilities	(466)
Goodwill	2,044
	$ 9,422

The acquisition of GmbH Group contributed revenue of $ 2.4 million and a loss of $14.6 million to the Company's results from May 7, 2019 through December 31, 2019. The goodwill is attributable to the workforce and will not be deductible for tax purposes.

The following unaudited supplemental pro forma information summarizes the results of operations of GmbH as if the acquisition had occurred on January 1, 2018:

	Period from January 1 to May 6, 2019
Revenue	$ 1,811
Net (loss) income	$ (6,880)

The goodwill is attributable to the workforce and will not be deductible for tax purposes.

Alpha

F-star Ltd issued 570,387 shares to acquire Alpha at a fair value of $ 13.5 million. The net assets acquired were comprised of cash, other current assets, and non-current liabilities. There were no tangible or intangible assets acquired.

6. Prepaid expenses and other current assets

Prepaid expenses and other current assets on December 31, 2020, and 2019 consist of the following (in thousands):

	2020	2019
Research and Development	$ 526	$1,382
Rent	705	220
Clinical Trial Costs	846	204
License Fees	—	608
VAT recoverable	443	842
Insurance	277	—
Refunds due	420	—
Other	759	332
	$3,976	$3,588

7. Property, plant and equipment, net

Property, plant and equipment, net consisted of the following (in thousands):

	2020	2019
Leasehold improvements	$ 15	$ 14
Laboratory equipment	1,788	1,725
Furniture and office equipment	169	194
	1,972	1,933
Less: Accumulated depreciation	1,183	508
	$ 789	$1,425

Depreciation expense was $1.1 million and $0.8 million for the year ended December 31, 2020 and 2019, respectively. During the year ended December 31, 2019, the Company disposed of property, plant and equipment with a gross book value and accumulated depreciation of less than $0.1 million. There was no material gain or loss resulting from the disposals.

8. Goodwill and In-process Research and Development

The changes in the carrying amount of Goodwill and In-process Research and Development were as follows (in thousands):

	Goodwill	In-process R&D
Amount acquired as of May 7, 2019	$ 4,337	17,395
Capitalized	—	127
Impairments during the year	—	(4,152)
Effect of changes in exchange rate used for translation	(17)	(321)
Balance at December 31, 2019	$ 4,320	$ 13,049
Capitalized	—	730
Acquired by the Transaction	10,451	4,720
Effect of changes in exchange rate used for translation	155	487
Balance at December 31, 2020	$14,926	$ 18,986

The Company's In-process R&D assets has been classified as indefinite-lived intangible assets.

9. Fair Value Measurements

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	Fair Value Measurements as of December 31, 2020 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Contingent value rights	$ —	$ —	$2,520	$2,520
Warrants	—	—	37	37
	$ —	$ —	$2,557	$2,557

The Company classified the contingent value rights within Level 3 because their fair values are determined using net present value techniques, based upon non-public information estimated by management. The fair value of the contingent value rights is based on the Company's probability-weighted discounted cash flow assessment that considers probability and timing of future payments. The fair value measurement is based on significant Level 3 unobservable inputs such as the probability of achieving a sale or licensing agreement, anticipated timelines, and discount rate.

	Fair Value Measurements as of December 31, 2019 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Convertible notes	$ —	$ —	$14,906	$14,906

The convertible notes were recorded at fair value upon the date of issuance and was subsequently remeasured to fair value at each reporting date. Immediately prior to the completion of the share exchange on November 20, 2020, the convertible notes were converted to 1,445,779 common shares. The principal amount and accrued interest at the date of conversion were $19.2 million and $1.0 million, respectively. The Company recognized a $2.4 million gain for the change in fair value of the convertible notes immediately prior to the conversion in the statement of operations and comprehensive loss, and the principal amount was recorded to equity.

The following table reflects the change in the Company's Level 3 liabilities, which consists of the liability based warrants outstanding as of November 20, 2020 through December 31, 2020 (in thousands):

	November 2016 Private Placement Warrants
Fair value of liability based warrants outstanding as of November 20, 2020	$ 221
Warrants exercised	(184)
Balance at December 31, 2020	$ 37

10. Accrued Expenses and Other Current Liabilities

Accrued expenses at December 31, 2020 and 2019 were comprised of the following (in thousands):

	2020	2019
Clinical Trial Costs	$3,394	$5,892
Severance	1,953	—
Compensation and Benefits	1,361	1,190
Professional Fees	1,593	1,305
Payroll taxes	—	257
Other	1,160	232
	$9,461	$8,876

11. Convertible Notes

F-star Ltd issued, 8% convertible notes on September 19, 2019, for $6.6 million, a second tranche issued on November 27, 2019, for $6.6 million, a third tranche issued on March 3, 2020, for $ 0.6 million and a final tranche issued on July 19, 2020, for $ 0.3 million. All notes were issued under the same terms.

The notes were convertible into a variable number of series A preference shares at the option of the holder together with interest outstanding, in the event F-star Ltd raised at least USD $50.0 million or there was a change of control. On expiry of the term, if no conversion notice has been issued, the notes would be redeemable at principal plus accrued interest.

The initial fair value of the convertible notes designated at fair value through profit and loss ("FVTPL") was determined as the transaction price, as this is deemed to be at arm's length in accordance with the guidance set out in ASC 825. Subsequent measurement of fair value was determined using a weighted average percentage probability of various possible scenarios for conversion of the notes. The key assumption in calculating the fair value of the embedded derivative as through the date conversion, was the probability of securing Series B financing of 90% with the balance of probability allocated to no funding and redemption on expiry (in which case the value of the derivative is zero).

Immediately prior to the completion of the share exchange on November 20, 2020, the convertible notes were converted to 1,445,779 common shares. The principal amount and accrued interest at the date of conversion were $19.2 million and $1.0 million, respectively. The Company recognized a $2.4 million gain for the change in fair value of the convertible notes immediately prior to the conversion in the statement of operations and comprehensive loss, and the principal amount was recorded to equity.

The following table provides a roll-forward of the fair values of the Company's convertible note for which fair value was determined by Level 3 inputs (in thousands):

Convertible notes at fair value	
Balance on December 31, 2019	$ 14,906
Proceeds from issuance	850
Interest	978
Effects of foreign exchange	29
Fair value gain	2,386
Conversion of notes to equity	(19,149)
Fair value at December 31, 2020	$ —

12. Warrants

In connection with Spring Bank's IPO in 2016, there was an issuance of warrants to the sole book-running manager to purchase 7,087 shares of common stock. The warrants are exercisable at an exercise price of $60.00 per share and expire on May 5, 2021. The Company evaluated the terms of the warrants and concluded that they should be equity-classified. At December 31, 2020, there were 7,087 warrants outstanding.

During 2016, Spring Bank entered into a definitive agreement with respect to the private placement of 411,184 shares of common stock and warrants to purchase 411,184 shares of common stock (the "November 2016 Private Placement Warrants") to a group of accredited investors. The November 2016 Private Placement Warrants are exercisable at an exercise price of $43.16 per share and expire on November 23, 2021. The Company evaluated the terms of these warrants and concluded that they are liability-classified. The Company must recognize any change in the value of the warrant liability each reporting period in the statement of operations and comprehensive loss. As of December 31, 2020, the fair value of the November 2016 Private Placement Warrants was approximately $37,000 and 340,137 warrants have been exercised to date. At December 31, 2020, there were 71,047 warrants outstanding

A summary of the Black-Scholes pricing model assumptions used to record the fair value of the warrants is as follows:

	2020
Risk-free interest rate	1.9%
Expected term (in years)	0.9
Expected volatility	100.0%
Expected dividend yield	0%

During 2019, Spring Bank entered into an agreement with Pontifax Medison Finance (Israel) L.P. and Pontifax Medison Finance (Cayman) L.P., as lenders, and Pontifax Medison Finance GP, L.P warrants to purchase 62,500 shares of common stock (the "Pontifax Warrants"). The Pontifax Warrants are exercisable at $8.32 per share and expire on September 19, 2025. The Company evaluated the terms of the warrants and concluded that they should be equity-classified. At December 31, 2020, there were 62,500 warrants outstanding.

During 2019, Spring Bank issued warrants to a service provider to purchase 3,750 shares of common stock (the "September 2019 Warrants"). The September 2019 Warrants are exercisable at an exercise price of $16.84 per share and expire on September 19, 2021. The Company evaluated the terms of the warrants and concluded that they should be equity-classified. At December 31, 2020, there were 3,750 warrants outstanding.

A summary of the warrant activity for the Company since the Closing Date of the Transaction to the year ended December 31, 2020 is as follows:

	Warrants
Warrant outstanding as of November 20, 2020	481,781
Exercises	(337,397)
Outstanding at December 31, 2020	144,384

13. Stock Option Plans

Incentive Plans

On June 14, 2019, as part of the group restructuring, the F-star Ltd board of directors and shareholders approved the 2019 Equity Incentive Plan (or the "2019 Plan"). The initial maximum number of ordinary shares that could be issued under the 2019 Plan was 2,327,736. This number consisted of 1,922,241 new ordinary shares and 405,495 new ordinary shares as replacements for grants under the previous F-star Group Entities legacy share options schemes (F-star Alpha Limited Share Option Scheme, the F-star Beta Share Option Scheme and the GmbH F-star EMI Share Option Scheme). In addition, the GmbH Employee Share option Plan ("ESOP plan") was transferred to F-star Ltd from GmbH. This plan grants the beneficiaries participation rights only, beneficiaries would receive a proportion of the exit proceeds realized by shareholders, but the plan does not grant the right to purchase shares. The transfer of the participation rights occurred at the same exchange ratio as used for the exchange of GmbH shares for shares issued by F-star Ltd.

Awards granted under the 2019 Plan generally vest over a four-year service period with 28% of the award vesting on the first anniversary of the commencement date and the balance vesting monthly over the remaining three years. Awards generally expire 10 years from the date of the grant. For certain senior members of management and directors, the board of directors approved an alternative vesting schedule. As of December 31, 2020, there were 33,778 shares available for issuance under the 2019 Plan.

In conjunction with the Transaction, all issued and outstanding F-star Ltd share options granted under F-star Ltd three legacy equity incentive plans became exercisable in full immediately prior to the Closing. At the Closing, all issued share options and restricted stock units (RSUs) granted by F-star Ltd under the F-star Therapeutics

Limited 2019 Equity Incentive Plan (F-star 2019 plan) were replaced by options ("Replacement Options") and awards ("Replacement RSUs"), on the same terms (including vesting), for Company common stock, based on the Exchange Ratio. The Company determined that the exchange of F-star Ltd awards for the Company awards would be accounted for as a modification of awards under ASC 718. The Company concluded that the modification will not affect the number of awards expected to vest or the service period over which compensation expense related to awards will be recognized since the vesting schedule applicable to each Replacement Option will be the same as the vesting schedule applicable to the original option that it replaces. In addition, the Replacement RSUs and Replacement Options will be subject to the same terms and conditions as the original RSUs and original options, respectively (except to the extent such terms are rendered inoperative because of the transactions contemplated by the Exchange Agreement) and will not provide holders of the Replacement Options or Replacement RSUs with any additional benefits that the holders did not have under their original options or original RSUs. In addition, the fair value of an award tranche immediately after modification was less than the fair value of that award tranche immediately before modification therefore total compensation cost that is recognized for the Replacement RSUs and Replacement Options equal the grant-date fair value of the original award and the Company will continue to recognize the grant date fair values of the modified awards over their respective service periods.

Amended and Restated 2015 Stock Incentive Plan

In March 2018, the Board approved the Amended and Restated 2015 Plan. Upon receipt of stockholder approval at the Company's 2018 annual meeting in June 2018, the 2015 Plan was amended and restated in its entirety increasing the authorized number of shares of common stock reserved for issuance by 800,000 shares (together with the 2014 Plan, the 2015 Plan, the "Stock Incentive Plans"). Pursuant to the Amended and Restated 2015 Plan, there are 1,666,863 shares authorized for issuance. In addition, to the extent any outstanding awards under the 2014 Plan expire, terminate or are otherwise surrendered, cancelled or forfeited after the closing of the Company's IPO, those shares are added to the authorized shares under the Amended and Restated 2015 Plan. The total amount of shares authorized for issuance under both the 2014 Plan and the Amended and Restated 2015 Plan is 2,300,000.

Pursuant to the Exchange Agreement, all outstanding options to purchase Company common stock were accelerated immediately prior to the Closing and each outstanding option with an exercise price less than the trading price of the Company common stock as of the close of trading on the Closing Date was exercised in full and all other outstanding options to purchase Company common stock were cancelled effective as of the Closing Date. As of December 31, 2020, the Company had 678,949 shares available for issuance under the Amended and Restated 2015 Plan.

Stock option valuation

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model with the following assumptions:.

	2020	2019
Risk-free interest rate	0.17% - 0.42%	1.74% - 1.85%
Expected volatility	82.8% - 98.3%	70.03 - 70.31%
Expected dividend yield	0%	0%
Expected life (in years)	5.1	5.1

Expected Term—The expected term represents management's best estimate for the options to be exercised by option holders.

Volatility—Since F-star Ltd did not have a trading history for its common stock, the expected volatility was derived from the historical stock volatilities of comparable peer public companies within its industry that are

considered to be comparable to F-star Ltd business over a period equivalent to the expected term of the share-based awards. After the closing of the Transaction, the volatility of the Company's Common Stock is used to determine volatility of the share-based awards at grant date.

Risk-Free Interest Rate—The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the share-based awards' expected term.

Dividend Rate—The expected dividend is zero as the Company has not paid nor does it anticipate paying any dividends on its common stock in the foreseeable future.

Fair Value of Common Stock— Prior to the Transaction, F-star Ltd estimated fair value used three different methodologies, the income approach, the market approach and cost approach. The income approach uses the estimated present value of economic benefits. The market approach exams observable market values for similar assets or securities. The cost approach uses the concept of replacement cost as an indicator of value and the notion that an investor would pay no more for an asset that what it would cost to replace the asset with one of equal utility. After the closing of the Transaction, the fair value of the Company's Common Stock is used to estimate the fair value of the share-based awards at grant date.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance on December 31, 2019	259,148	$ 7.07	9.24	$ 4,334
Granted	415,343	0.20	—	—
Exercised	(42,260)	0.10	—	—
Forfeited	(28,883)	4.79	—	—
Outstanding as of December 31, 2020	603,348	$ 2.94	9.30	$ 8,494
Options exercisable at December 31, 2020	89,957	$ 9.24	8.70	$ 1,228

The weighted average grant date fair value of options granted during the year ended December 31, 2020 and 2019, was $ 14.45 and $23.94 per share, respectively. The total fair value of options vested during the years ended December 31, 2020, and 2019, was $2.0 million and $1.6 million, respectively.

Share-based compensation

The Company recorded share-based compensation expense in the following expense categories for the year ended December 31, 2020 and 2019 of its consolidated statements of operations and comprehensive loss (in thousands):

	2020	2019
Research and development expenses	$ 684	$ 554
General and administrative expenses	2,805	2,115
	$3,489	$2,669

As of December 31, 2020, and 2019, the total unrecognized compensation cost relating to unvested options granted was $ 5.1 million and $2.7 million, respectively, which is expected to be realized over a period of 3.2 years and 2.9 years, respectively. The Company will issue shares upon exercise of options from shares reserved under the Plan.

14. Significant agreements

License and Collaboration agreements

For the years ended December 31, 2020 and 2019, the Company had License and Collaboration agreements ("LCA"s) with Denali Therapeutics Inc. ("Denali") and Ares Trading S.A ("Ares"). The following table summarizes the revenue recognized in the Company's consolidated statements of operations and comprehensive loss from these arrangements, (in thousands):

	Year Ended December 31,	
	2020	2019
Collaboration revenues		
Ares (Switzerland)	$ 9,930	$25,871
Denali (US)	1,326	2,450
Total collaboration revenues	**$11,256**	**$28,321**

License and collaboration agreement with Denali Therapeutics Inc.

Summary

In August 2016, F-star Biotechnology Limited, F-star Gamma Limited (a related party until May 30, 2018) ("F-star Gamma"), and f-star Biotechnologische Forschungs-und Entwicklungsges.m.b.H entered into a license and collaboration agreement (the "Denali LCA") with Denali Therapeutics Inc. ("Denali"). The goal of the collaboration was the development of certain constant Fc domains of an antibody with non-native antigen binding activity ("Fcabs"), to enhance delivery of therapeutics across the blood brain barrier into the brain. The collaboration was designed to leverage the Company's modular antibody technology and Denali's expertise in the development of therapies for neurodegenerative diseases. In connection with the entry into the collaboration agreement, Denali also purchased from the F-star Gamma shareholders an option, which was referred to as the buy-out-option, to acquire all of the outstanding shares of F-star Gamma pursuant to a pre-negotiated share purchase agreement.

On May 30, 2018, Denali exercised such buy-out option and entered into a share purchase agreement, or the Purchase Agreement, with the shareholders of F-star Gamma and Shareholder Representative Services LLC, pursuant to which Denali acquired all of the outstanding shares of F-star Gamma, or the Acquisition.

As a result of the Acquisition, F-star Gamma has become a wholly owned subsidiary of Denali and Denali changed the entity's name to Denali BBB Holding Limited. In addition, Denali became a direct licensee of certain of the Company's intellectual property (by way of Denali's assumption of F-star Gamma's license agreement with the Company, or the F-star Gamma License). Denali made initial exercise payments to the Company and the former shareholders of F-star Gamma under the Purchase Agreement and the F-star Gamma License in the aggregate, of $18.0 million, less the net liabilities of F-star Gamma, which were approximately $0.2 million. $4.0 million was payable to the Company. In addition, Denali is required to make future contingent payments, to the Company and the former shareholders of F-star Gamma, with a maximum aggregate of $437.0 million upon the achievement of certain defined preclinical, clinical, regulatory and commercial milestones. Of this total, a maximum of $91.4 million is payable to the Company. The total amount of the contingent payments varies, based on whether the Company delivers an Fcab that meets pre-defined criteria and whether the Fcab has been identified solely by the Company or solely by Denali or jointly by the Company and Denali.

Under the terms of the Denali License and Collaboration Agreement, Denali has the right to nominate up to three Fcab targets for approval ("Accepted Fcab Targets"), within the first three years of the date of the Denali License and Collaboration Agreement. Upon entering into the Denali License and Collaboration Agreement, Denali had

selected transferrin receptor, or TfR, as the first Accepted Fcab Target and paid an upfront fee of $ 5.5 million to F-star Gamma, which included selection of the first Accepted Fcab Target. In May 2018, Denali exercised its right to nominate two additional Fcab targets and identified a second Accepted Fcab Target. Denali made a one-time payment to the group for the two additional Accepted Fcab Targets of $6.0 million and extended the time period for its selection of the third Accepted Fcab Target until August 2020.

Denali is also responsible for certain research costs incurred by the Company in conducting activities under each agreed development plan, for up to 24 months.

Under the terms of the Denali License and Collaboration Agreement, the Company is prohibited from developing, commercializing and manufacturing any antibody or other molecule that incorporates any Fcab directed to an Accepted Fcab Target, or any such Fcab as a standalone product, and from authorizing any third party to take any such action.

Revenue recognition

The Company has considered the performance obligations identified in the contracts and concluded that the grant of intellectual property rights is not distinct from the provision of R&D services, as the R&D services are expected to significantly modify the early-stage intellectual property. As a result, the grant of intellectual property rights and the provision of R&D services has been combined into a single performance obligation for this contract.

The initial transaction price for first Accepted Fcab Target was deemed to be $ 7.1 million consisting of $5.0 million for the grant of intellectual property rights and $2.1 million for R&D services, and $5.1 million for the second Accepted Fcab Target consisting of $ 3.0 million for the grant of intellectual property rights and $2.1 million for R&D services.

During the year ended December 31, 2019, the transaction price for the first accepted Fcab was increased to $ 6.6 million due to achievement of a $1.5 million milestone that on initial recognition of the contract was not included in the transaction price, as it was not deemed probable that a reversal would not occur in a future reporting period. The Company recognized the $1.5 million at a point in time. No other revenue was recognized for the first accepted Fcab in the year as the performance obligation identified in the contract was deemed to have been fully satisfied prior to May 7, 2019, the date of acquisition of F-star Biotechnology.

During the years ended December 31, 2020 and 2019 the Company recognized $ 1.3 million and $0.9 million respectively over time in respect of the second Fcab target.

2019 License and collaboration agreement with Ares Trading S.A.

In June 2017, Delta entered into a License and Collaboration Agreement (“LCA”) and an Option Agreement with Ares Trading S.A (“Ares”). The purpose of the LCA was for the companies to collaborate on the development of tetravalent bispecific antibodies against five drug target pairs. The Option Agreement granted Ares a call option to acquire the entire issued share capital of Delta. Under the LCA the company was obligated to use commercially reasonable efforts to perform R&D activities on the five selected target pairs, under mutually agreed research plans. The activities were governed by a joint steering committee formed by an equal number of representatives from both parties.

On May 14, 2019, the LCA agreement with Ares was amended and restated to convert the existing purchase option over the entire share capital of Delta to an intellectual property licensing arrangement that includes the exclusive grant of development and exploitation rights to one tetravalent bispecific antibody directed against immuno-oncology targets and the option to acquire the exclusive right to an additional antibody. As part of the amended LCA, Delta now has exclusive rights to FS118, its lead product candidate, which is currently in a proof-of-concept clinical trial. As noted in the subsequent section of this footnote, this amended and restated LCA was accounted for a separate contract, rather than a contract amendment.

For the exclusive rights granted in relation to the first molecule, an option fee of $ 11.1 million was paid by Ares to Delta. Following receipt of the option fee, Ares becomes responsible for the development of the molecule and development, regulatory and sales-based royalties become payable to Company upon achievement of specified events. The Company is eligible to receive $71.6 million in development milestones and $83.9 million in regulatory milestones.

For the second antibody included within the amended and restated agreement, Delta is obliged to perform research activities under plans agreed by both parties. Ares will pay for all R&D costs half-yearly in advance until the company delivers the data package specified in the research plan. Ares can then elect to pay a fee of $14.0 million to exercise their option to take an exclusive intellectual property license, which allows them to control the development and exploitation of the molecule. Following receipt of the option fee, Ares is responsible for the development of the molecule and development, regulatory and sales-based royalties become payable to Delta upon achievement of specified events. Delta is eligible to receive $48.7 million in development milestones and $61.6 million in regulatory milestones.

Development milestone payments are triggered upon achievement by each product candidate of a defined stage of clinical development and regulatory milestone payments are triggered upon approval to market a product candidate by the FDA or other global regulatory authorities. Sales-based milestones are payable based upon aggregate annual worldwide net sales in all indications of all licensed products. The company is eligible to receive $168.0 million in sales-based milestones. In addition, to the extent that any product candidates covered by the exclusive licenses granted to Ares are commercialized, the company will be entitled to receive a single digit royalty based on a percentage of net sales on a country-by-country basis.

On July 15, 2020 (“2020 Amendment”), a deed of amendment was enacted in respect of the May 14, 2019, License and Collaboration agreement between the group and Ares Trading S.A. The amendment had two main purposes (i) to grant additional options to acquire intellectual property rights for a further two molecules; and (ii) to allow Ares to exercise its option early to acquire intellectual property rights to the second molecule included in the agreement as well as to terminate the R&D services.

Revenue recognition

Management has considered the performance obligations identified in the contracts and concluded that the option for the grant of intellectual property rights is not distinct from the provision of R&D services in the agreements, as the R&D services are expected to significantly modify the early-stage intellectual property. As a result, the option for the grant of intellectual property rights and the provision of R&D services has been combined into a single performance obligation for all molecules under the original contract and each individual molecule included in the May 14, 2019, amendment. The Company recognizes revenue using the cost-to-cost method, which it believes best depicts the transfer of control of the services to the customer. Under the cost-to-cost method, the extent of progress towards completion is measured based on the ratio of actual costs incurred to the total estimated costs expected upon satisfying the identified performance obligation.

In the year ended December 31, 2019, $13.3 million Licensing and R&D services revenue relating to the five antibodies included in the original LCA was recognized, based on the cost-to-cost method.

All performance obligations in the original contract were deemed to have been fully satisfied on termination of the agreement on May 14, 2019, and no further revenue is expected to be recognized.

The total transaction price for the amended and restated LCA was initially determined to be $ 15.4 million, consisting of the upfront payment and R&D funding for the research term. Variable consideration to be paid to the company upon reaching certain milestones had been excluded from the calculation, as at the inception of the contract, it was not probable that a significant reversal of revenue recognized would not occur in a subsequent reporting period.

In the year ended December 31, 2019, $11.1 million Licensing and R&D services revenue for the first antibody included within the amended and restated LCA was recognized at a point in time, as no further performance obligations were identified. Licensing and R&D services revenue of $1.4 million for the second antibody included within the amended and restated LCA was recognized, based on the cost-to-cost method.

There were two components identified in the 2020 amendment, each of which was accounted for as a separate performance obligation. The grant of the additional options to acquire intellectual property rights was deemed to be distinct, as the customer can benefit from it on its own, and it is independent of the delivery of other performance obligations in the original contract. Additionally, as the amount of consideration reflects a standalone selling price, the Company determined that the second component is accounted for as a separate contract.

The second component that allows the customer to exercise its option to acquire intellectual property rights early is considered to be a modification of the original contract, as the option is not independent of the R&D services provided under the original contract, and therefore the goods and services are not distinct. The Company updated the transaction price and measure of progress for the performance obligation relating to this molecule. All performance obligations under the May 13, 2019 agreement in respect of the second molecule were deemed to have been fully satisfied on July 15, 2020 and the option fee of $8.5 million was recognized in full when the option was exercised on the date of modification. R&D services of $1.4 million were also recognized in the year ended December 31, 2020 prior to the July 15 deed of amendment.

As a result of this amendment, the maximum amount payable by Ares Trading S.A on the achievement of certain development and regulatory milestones in the aggregate is increased to $501.7 million, and the maximum amount payable on the achievement of certain commercial milestones is increased to $309.5 million.

On March 26, 2021, Ares provided notice of its intention to exercise its option granted under the 2020 Amendment to acquire the intellectual property rights for an additional molecule. An option fee of $3.1 million is payable upon option exercise.

Summary of Contract Assets and Liabilities

Up-front payments and fees are recorded as deferred revenue upon receipt or when due until such time as the Company satisfies its performance obligations under these arrangements. A contract asset is a conditional right to consideration in exchange for goods or services that the Company has transferred to a customer. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional.

The following table presents changes in the balances of the Company's contract assets and liabilities (in thousands):

Year ended December 31, 2020	Balance at beginning of year	Additions	Recognized	Impact of exchange rates	Balance at end of year
Contract liabilities:					
Ares collaboration	$ 33	$ 37	$ (33)	$ —	$ 37
Denali collaboration	409	—	(151)	5	263
Total deferred revenue	**$ 442**	**$ 37**	**$ (184)**	**$ 5**	**$ 300**

Year ended December 31, 2019	Balance at beginning of year	Acquired with Subsidiaries	Additions	Recognized	Impact of exchange rates	Balance at end of year
Contract liabilities:						
Ares collaboration	$ 5,824	$ —	$ —	$ (5,903)	$ 112	$ 33
Denali collaboration	—	869	31	(473)	(18)	409
Total deferred revenue	**$ 5,824**	**$ 869**	**$ 31**	**$ (6,376)**	**$ 94**	**$ 442**

During the years ended December 31, 2020, and 2019, all revenue recognized by the Company as a result of changes in the contract liability balances in the respective periods was based on proportional performance.

15. Income Taxes

For the years ended December 31, 2020, and 2019, the Company recognized an immaterial total income tax benefit and a total income tax benefit of $0.7 million, respectively. The Company is subject to corporate taxation in the United Kingdom, United States and Austria. The Company's income tax benefit provision in the year ended December 31, 2020 is mainly the result of US federal branch taxes and a prior year adjustment in Austria. The income tax benefit in the year ended December 31, 2019 is mainly the result of the reduction in deferred tax liabilities arising on acquired IPR&D assets due to the intangible asset impairment. The components of net (loss)/profit before tax provision from income taxes are as follows (in thousands):

	Year Ended December 31,	
	2020	2019
United Kingdom	$(24,490)	$(20,943)
Austria	315	(62)
United States	(1,445)	(2,745)
Total	$(25,620)	$(23,750)

The components of the benefit for income taxes are as follows (in thousands):

	Year Ended December 31,	
	2020	2019
Federal	$ (41)	$ (152)
State	—	(7)
Foreign	42	—
Total current income tax (provision) benefit	1	(159)
Total deferred income tax (benefit)	—	896
Total benefit from income taxes	$ 1	$ 737

The Company is subject to the corporate tax rate in the United States. In the year ended December 31, 2019 the Company was subject to the rate of corporate tax in the United Kingdom (19%) due to the ultimate parent entity (FTL) being UK-domiciled. The following table summarizes a reconciliation of income tax benefit compared with the amounts at the United States statutory income tax rate:

	Year Ended December 31,	
	2020	2019
Income tax (provision) benefit at statutory rate	21.0%	19.0%
Expenses not deductible	(9.4%)	(8.5%)
Net losses surrendered for U.K. R&D tax credit	(4.6%)	(10.3%)
Change in valuation allowance	(7.1%)	3.8%
Foreign rate differential	(1.5%)	(0.1%)
Adjustment in respect to prior years	1.6%	(0.8%)
Actual income tax expense effective tax rate	0.0%	3.1%

The (provision) benefit for income taxes shown on the consolidated statements of operations differs from amounts that would result from applying the statutory tax rate to income before taxes primarily because of certain non-deductible expenditures, net operating losses surrendered for the U.K. R&D tax credit, and the change in the Company's valuation allowance on its deferred tax assets.

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Significant components of the Company's current and deferred tax assets (liabilities) as at December 31, 2020 and 2019, were as follows (in thousands):

	Year Ended December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 45,053	$ 9,403
Research and development credit carryforwards	957	—
Capitalized R&D expenditures	5,238	—
Lease Obligation	860	—
Stock option expense	1,206	742
Other	18	—
Total gross deferred tax assets	$ 53,332	$ 10,145
Valuation Allowance	(49,304)	(7,607)
Net deferred tax assets	4,028	2,538
Deferred tax liabilities:		
Acquired Intangibles	(3,763)	(2,205)
Right of Use Assets	(769)	—
Capital Allowances	(72)	(333)
Net deferred tax liability	**$** (576)	**$** —

The Company regularly assesses its ability to realize its deferred tax assets. Assessing the realization of deferred tax assets requires significant judgment. In determining whether its deferred tax assets are more likely than not realizable, the Company evaluated all available positive and negative evidence, and weighed the evidence based on its objectivity. After consideration of the evidence, including forecasts and strategic plans, management has concluded that it is more likely than not that the Company will not realize the benefits of its deferred tax assets and accordingly the Company has provided a valuation allowance for the full amount of the net deferred tax assets.

The Company intends to continue to maintain a full valuation allowance on its deferred tax assets until there is sufficient evidence to support the reversal of all or some portion of these allowances. The release of the valuation allowance would result in the recognition of certain deferred tax assets and an increase to the benefit for income taxes for the period the release is recorded. However, the exact timing and amount of the valuation allowance release are subject to change on the basis of the level of profitability that the Company is able to actually achieve.

Management has determined that it is more likely than not that the Company will not recognize the benefits of its federal, state, and foreign deferred tax assets, and as a result, a valuation allowance of $49.3 million and $7.6 million has been established at December 31, 2020, and 2019, respectively. In the year ended December 31, 2020 the increase in the valuation allowance was $41.7 million, which was mainly due to the acquisition of net operating loss and research and development credit carryforwards acquired as part of the share exchange with Spring Bank. In the year ended December 31, 2019 the increase of $7.5 million was primarily due to the acquisition of NOLs due to the 2019 reorganization. At December 31, 2020, the Company had federal, state, and foreign NOL carryforwards of $125.8 million, $126.5 million, and $48.9 million, respectively, which expire beginning in 2030. The Company's unsurrendered U.K. and Austrian net operating losses, and its U.S. federal net operating losses generated after December 31, 2017, do not expire.

The Internal Revenue Code of 1986, as amended (the Code), provides for a limitation of the annual use of net operating losses and other tax attributes (such as research and development tax credit carryforwards) following certain ownership changes (as defined by the Code) that could limit the Company's ability to utilize these

carryforwards. At this time, the Company has not completed a study to assess whether an ownership change under Section 382 of the Code has occurred, or whether there have been multiple ownership changes since the Company's formation. The Company may have experienced ownership changes, as defined by the Code, as a result of past transactions. Accordingly, the Company's ability to utilize the aforementioned carryforwards may be limited. In addition, U.S. tax laws limit the time during which these carryforwards may be applied against future taxable income and tax, respectively. Therefore, the Company may not be able to take full advantage of these carryforwards for federal or state income tax purposes.

U.K. and Austrian losses may be utilized to offset future taxable profits, subject to numerous utilization criteria and restrictions. The amount that can be offset each year is limited to £5.0 million plus an incremental 50% of U.K. taxable profits. In Austria, carried forward tax losses can be offset in the current year only up to a maximum of 75% of taxable income. As of December 31, 2020, the Company had federal and state research and development tax credit carryforwards of $0.3 million and $0.8 million, respectively, which expire beginning in 2031.

The Company files income tax returns in the United Kingdom, in Austria and in the United States for federal income taxes and in the Commonwealth of Massachusetts for state income taxes. In the ordinary course of business, the Company is subject to examination by tax authorities in these jurisdictions. The 2019 tax year remains open to examination by HM Revenue & Customs. The statute of limitations for assessment with the Internal Revenue Service is generally three years from filing the tax return. As such, all years since inception in the U.S. remain open to examination. The statute of limitation for assessment with the Austrian tax authorities is a period of five years following the end of each fiscal year. Therefore, all fiscal years from 2016 to 2020 remain open for assessment. The Company is currently not under examination by any jurisdictions for any tax years.

The Company recognizes, in its consolidated financial statements, the effect of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination. The Company had no uncertain tax positions during the years ended of December 31, 2020, and 2019. There are no amounts of interest or penalties recognized in the consolidated statement of operations or accrued on the consolidated balance sheets for any period presented. The Company does not expect any material changes in these uncertain tax benefits within the next 12 months.

The Company recognizes interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2020, and 2019, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's statements of operations and comprehensive loss.

16. Net loss per share

The following table summarizes the computation of basic and diluted net loss per share of the Company for such years (in thousands, except share and per share data):

	2020	2019
Net loss	$ (25,619)	$ (23,013)
Weighted average number shares outstanding, basic and diluted	2,643,175	1,545,177
Net loss income per common, basic and diluted	$ (9.69)	$ (14.89)

Diluted net loss per common share is the same as basic net loss per common share for all years presented.

For the year ended December 31, 2020, 501,255 potential stock options have been excluded from diluted earnings per share due the net loss and 102,093 stock options are anti-dilutive and have been excluded from the diluted earnings per share computation as the exercise prices of these common shares were above the market price of the common stock for the years indicated. For the year ended December 31, 2019, the weighted average number of potentially dilutive shares was 205,874.

17. Commitments and Contingencies

Lease Obligations

On January 27, 2021, the Company signed an operating lease for three years for its corporate headquarters in Cambridge, UK. The Company also has leases for the former Spring Bank headquarters and laboratory space in Hopkinton, Massachusetts which are being subleased. The Company's leases have remaining lease terms of approximately 7.8 years for its former principal office and laboratory space, which includes an option to extend the lease for up to 5 years, and approximately 0.5 years for its former headquarters. The Company's former headquarters location is being subleased through the remainder of the lease term.

As of December 31, 2020, and 2019, the weighted average discount rate for operating leases was 5% and 8%, respectively.

Operating lease costs under the leases for the year ended December 31, 2020 and 2019, were approximately $ 0.3 million and $0.4 million. Total operating lease costs for the year ended December 31, 2020, were offset by an immaterial amount for sublease income.

The following table summarizes the Company's maturities of operating lease liabilities as of December 31, 2020 (in thousands):

Year	
2021	$ 542
2022	451
2023	462
2024	474
2025	486
Thereafter	1,444
Total lease payments	$3,859

Sublease

The Company subleases two former Spring Bank offices in Hopkinton, Massachusetts. Operating sublease income under operating lease agreements for the year ended December 2020 was immaterial. These subleases have remaining lease terms of 0.4 years and 7.6 years. Future expected cash receipts from subleases as of December 31, 2020 is as follows (in thousand):

Year	
2021	$ 83
2022	462
2023	474
2024	486
2025	498
Thereafter	1,482
Total sublease receipts	$3,485

Service Agreements

As of December 31, 2020, and 2019, the Company has contractual commitments of $ 4.7 million and $1.0 million, respectively with a contract manufacturing organization ("CMO") for activities that are ongoing or are scheduled to start between 3 and 9 months of the date of the statement of financial position. Under the terms of the agreement with the CMO, the Company is committed to pay for some activities if those activities are cancelled up to 3, 6 or 9 months prior to the commencement date.

Contingencies – stockholder litigation due to the share exchange

The following are contingent liabilities of the Company that were acquired on November 20, 2020:

On September 3, 2020, a Spring Bank stockholder filed a complaint in the United States District Court for the Southern District of New York (Lenthall v. Spring Bank Pharmaceuticals, Inc. et al, Case No. 1:20-cv-07219 (S.D.N.Y.)), against Spring Bank and the members of Spring Bank's Board of Directors (the "individual defendants"), alleging violations of Section 14(a) of the Exchange Act and Rule 14a-9 promulgated thereunder, and as against the individual defendants, alleging violations of Section 20(a) of the Exchange Act and of Delaware state law. The plaintiff alleges that the defendants made materially misleading disclosures in Spring Bank's Form S-4 registration statement filed in connection with the Exchange (the "Form S-4"), by allegedly omitting material information with respect to (i) financial projections relating to Spring Bank and F-star Ltd, (ii) Ladenburg's fairness opinion and any financial analyses conducted on Spring Bank. The plaintiff in Lenthall sought declaratory and injunctive relief to enjoin the Exchange as well as damages and attorneys' and experts' fees. While the Company believes there is no merit to this complaint, in March 2021, the Company executed a settlement agreement relating to this matter for an amount that is immaterial to the financial statements.

On September 8, 2020, in the United States District Court for the District of Delaware, a purported class action (Adam Franchi v. Spring Bank Pharmaceuticals, Inc. et al, Case No. 1:20-cv-01198 (D. Del.)) was filed against Spring Bank, members of Spring Bank's Board of Directors and F-star Ltd, alleging violations of Section 14(a) of the Exchange Act and Rule 14a-9 promulgated thereunder, and as against the individual defendants, alleging violations of Section 20(a) of the Exchange Act. This complaint alleged that the defendants made materially misleading disclosures in the Form S-4 by allegedly omitting material information with respect to (i) financial projections relating to Spring Bank and F-star Ltd, (ii) the confidentiality agreements entered into by Spring Bank prior to its engagement of Ladenburg, (iii) the process leading up to the execution of the Exchange Agreement and (iv) any financial analyses performed by Ladenburg. The plaintiff in Franchi sought declaratory and injunctive relief to enjoin the Exchange; or in the event of consummation of the Exchange, rescissory damages against the defendants; filing by the defendants of a Registration Statement deemed not to be materially misleading by the plaintiff; and attorneys' and experts' fees. While the Company believes there is no merit to this complaint, in March 2021, the Company executed a settlement agreement relating to this matter for an amount that is immaterial to the financial statements.

On September 18, 2020, in the United States District Court for the Southern District of New York, another Spring Bank stockholder filed a complaint (Arshad v. Spring Bank Pharmaceuticals, Inc., et al., Case No. 1:20-cv-07723 (S.D.N.Y.)), against Spring Bank and the members of Spring Bank's Board of Directors, alleging violations of Section 14(a) of the Exchange Act and Rule 14a-9 promulgated thereunder, and as against the individual defendants, alleging violations of Section 20(a) of the Exchange Act. The plaintiff alleged that the defendants made materially misleading disclosures in the Form S-4 by allegedly omitting material information with respect to (i) financial projections relating to Spring Bank and F-star Ltd, (ii) Ladenburg's fairness opinion and (iii) the process relating to the Exchange. The plaintiff in Arshad sought declaratory and injunctive relief to enjoin the Exchange; or in the event of consummation of the Exchange, rescissory damages against the defendants; filing by the defendants of a Registration Statement deemed not to be materially misleading by the plaintiff; and attorneys' and experts' fees. While the Company believes there is no merit to this complaint, in March 2021, the Company executed a settlement agreement relating to this matter for an amount that is immaterial to the financial statements.

On October 29, 2020, in the United States District Court Eastern District of New York, another Spring Bank stockholder filed a complaint (Nowakowski v. Spring Bank Pharmaceuticals, Inc., et al., Case No. 1:20-cv-05219 (E.D.N.Y.)), against Spring Bank and the members of Spring Bank's Board of Directors, alleging violations of Section 14(a) of the Exchange Act and Rule 14a-9 promulgated thereunder, and as against the individual defendants, alleging violations of Section 20(a) of the Exchange Act. The plaintiff alleges that the defendants made materially misleading disclosures in the Form S-4 by allegedly omitting material information with respect

to (i) financial projections relating to Spring Bank and F-star Ltd, (ii) Ladenburg's fairness opinion and (iii) the process relating to the Exchange. The plaintiff in Nowakowski sought rescissory damages against the defendants; declaration that defendants violated Sections 14(a) and 20(a) of the Exchange Act, and Rule 14a-9 promulgated thereunder; and attorneys' and experts' fees. This complaint was voluntarily dismissed on January 11, 2021.

18. Employee Plans

The Company provides a defined contribution plan for its employees in the United Kingdom and United States, pursuant to which the Company may match employees' contributions each year. During each of the years ended December 31, 2020, and 2019, the Company made contributions totaling $0.6 million.

19. Related Party Transactions 2019 reorganization

The transactions that resulted in the 2019 reorganization, in the year ended December 31, 2019, are deemed to be related party transactions by virtue of common directorships between the entities. There were no related party transactions for 2020.

Key management personnel (including directors)

During the year ended December 31, 2020 and 2019, the Company had purchases totaling none and $0.2 million, respectively, from Avacta Life Sciences Limited, a company in which the Company's Chief Executive Officer also holds a directorship. As of December 31, 2020, and 2019, the amounts outstanding and included in trade and other payables was none and $0.1 million, respectively.

On February 28, 2019, the F-star Ltd entered into a sub-lease rental arrangement with US-based company, Triplet Therapeutics, Inc.

A non-executive director of the Company also serves as the Chief Executive Officer of Triplet Therapeutics, Inc. The lease was terminated on December 31, 2019. Concurrently, the Company no longer acts as a lessor from this date and there are no material ongoing commitments with respect to this lease. Income from Triplet Therapeutics totaled $0.1 million for the year ended December 31, 2019, in respect of office rental and related office costs.

Related party transactions prior to 2019 reorganization

A summary of related party transactions for the year ended December 31, 2019, where exemption from reporting transactions and balances between group undertakings is unavailable under ASC 850 'Related Party Disclosures', are disclosed below. For the year ended December 31, 2019, only transactions prior to the group reorganization on May 7, 2019, are disclosed.

Some of the directors of Delta were also directors of Beta as well as members of the supervisory board of GmbH, which has a wholly owned subsidiary, F-star Biotechnology Limited.

Delta, Beta and F-Star Biotechnology Limited entered into an intellectual property license agreement and a support services agreement whereby Delta sub-licensed certain intellectual property rights from F-star Biotechnology Limited, via a sublicense to Beta. F-star Biotechnology Limited agreed to provide support services to Beta. Transactions in the year ended December 31, 2019 with Beta and F-star Biotechnology Limited were as follows (in thousands):

	2019	
	R&D recharges	Other recharges
Expenses		
Beta	$ 2,126	$ 552
F-star Biotechnology Limited	235	—
GmbH	—	13

R&D recharges relate to research paid for by Delta and carried out by F-star Biotechnology Limited, under the terms of its agreement with Beta.

These research services are based on time incurred and are charged on an FTE basis.

In addition, certain non-employment related costs associated with the research activities of Delta were incurred by F-star Biotechnology Limited and recharged back to Delta. GmbH invoiced Delta for its portion of board costs.

20. Subsequent events

On March 26, 2021, Ares provided notice of its intention to exercise its option granted under the 2020 Amendment to acquire the intellectual property rights for an additional molecule. An option fee of $3.1 million is payable upon option exercise.