MOSSADAMS

Under the Microscope

An Analysis of SEC Comment Letter Trends
Among Middle-Market and Pre-IPO Life Sciences Companies

CONTENTS

OVERVIEW

Initial public offering (IPO) activity in the life sciences industry maintained significant traction in 2019 and 2020, even amid pandemic-driven volatility in the early part of the year.

PERFORMANCE RECAP

A total of 60 companies in the life sciences industry went public in 2019, which is down by roughly 11% from 2018, as per Fenwick & West's IPO market review. Over 34 IPOs were recorded in the first half of 2019, with the deal count correspondingly standing at 26 for the second half of the year.

In terms of size, around 65% of IPOs raised between $25 million and $100 million in the second half of 2019, and another 27% raised between $125 million and $200 million. This momentum came under tight grips in early 2020 as the COVID-19 pandemic halted lives and livelihoods across the world.

IPO activity rebounded after a brief lull in March and April, with 33 life sciences offerings being registered in the first half of 2020. Aggregate deal size increased in comparison to the second half of 2019, with over 75% of companies raising $100 million or more. Out of this, two companies raised more than $1 billion each, becoming megadeals of the season.

One of the impacts of the COVID-19 pandemic was to drive a greater interest in disease-control solutions, helping fuel higher average IPO returns.

Despite the COVID-19 pandemic, and uncertainty in the capital markets, there remained significant investor interest in health care programs and policies, which impacted, and will continue to impact, the timing of life sciences deals for 2021.

KEY TRENDS IN THE INDUSTRY

With the development and subsequent approval of various COVID-19 vaccines, public attention is focused on the nature and status of health care in the country. This attention will likely persist, leading to ongoing support for the exploration of novel solutions, investment in patent protection, and continued innovation of products and markets.

The entire industry is making revolutionary changes, leading to value creation in multiple aspects—whether it be reengineering supply chains, creating personalized health care systems, or delving into digital transformation as demand for telehealth and smart monitoring and diagnostic tools gain greater footing.

Smart and Specialized R&D

The Food and Drug Administration (FDA) approved 48 new drugs in 2019, which includes a wide range of new modalities—like antibody-drug conjugates and oligonucleotides. This is slightly down from the record-breaking 59 new drugs approved in 2018. There has been an influx of innovative therapies for both chronic and underserved diseases, as players look toward undertaking specialized R&D and addressing a larger part of their addressable markets.

Integration of smart technology—from lab equipment to in-patient monitors and management tools—has also improved the speed and quality of drug research,

allowing for specialized trials and data gathering. This creates an efficient R&D chain that keeps the pipeline running smoothly and effectively.

These dynamics were observed in the 2019–2020 Securities and Exchange Commission (SEC) filings as well, with R&D, previously a key topic of focus, increasingly coming under added scrutiny.

Within a majority of the studied filings that were S-1 prospectuses, the emphasis on making adequate disclosures and clarifications in a range of R&D areas—drug development, clinical trials, pipelines, and current and upcoming products—remained paramount.

Electronic Security Tokens

Innovation wasn't just limited to biotechnology products and services. New access to capital was facilitated by digital accelerators. A key development here is the Biotech Electronic Security Token (BEST) by Agenus Inc., which is a tool based on blockchain technology that enables accredited investors to invest in specific late-stage products.

Unlike traditional debt and equity financing, BEST allows investors to limit exposure to a specific set of biotech products while at the same time enabling companies to preserve shareholder equity.

Given the huge costs and relatively long gestation periods associated with the life sciences industry—where each product has a unique risk and reward profile—digital tokens like these could gain greater acceptance as a preferred funding route.

The SEC started its examination of electronic security tokens in its 2019–2020 comment letters, requiring an unambiguous disclosure for how exactly the platform will be managed and accounted. While the scope of related scrutiny was limited to date, it could steadily increase as this financing route becomes more widespread.

Information Clarity and Effective Disclosure

Information accuracy, clarity, and transparency remain of utmost importance. SEC examination of information symmetry, adequacy, and effectiveness continued to be a key focus in 2019–2020, with many registrants asked to reevaluate the quantum and language of their statements—especially those made in relation to product description, efficacy, and market standing.

As part of the SEC's initiative to modernize reporting, amendments relating to the description of business, legal proceedings, and risk factors disclosures—under Regulation S-K—became effective on November 9, 2020. The intent is to improve and simplify companies' disclosures, aligning them and facilitating utility for the current business world.

SEC COMMENT LETTER REPORT RATIONALE

The objective of SEC comments is to keep market confidence intact by helping companies prevent discrepancies and bring greater transparency to investors.

The rationale of this SEC comment letter report is to identify, understand, and analyze comments made by the SEC in the past, in order to derive insights and encourage proactive preparedness for SEC registrants.

This report specifically examines SEC comments related to Forms S-1, 10-K, 10-Q, and 20-F filings in 2019–2020, identifying possible patterns and changes in SEC staff focus in relation to the last study of 2018–2019.

METHODOLOGY

To perform our analysis, we categorized all SEC comments issued to companies in select life sciences subindustries during the review period. The following subindustries were covered in our analysis, identified by the SEC's electronic data gathering, analysis, and retrieval system (EDGAR) Standard Industrial Classification (SIC) code.

FIGURE 1: Subindustry EDGAR SIC Codes

2833	Medical chemicals and botanical products
2834	Pharmaceutical preparations
2835	In vitro and in vivo diagnostics substances
2836	Biological products (no diagnostic substance)
3826	Laboratory analytical instruments
3841	Surgical and medical instruments and apparatus
3842	Orthopedic, prosthetic, and surgical appliances and supplies
3843	Dental equipment and supplies
3844	X-ray apparatuses, tubes, and related irradiation apparatuses
3845	Electromedical and electrotherapeutic apparatus
3851	Ophthalmic goods
8731	Commercial physical and biological research

Because middle-market companies were the focus of our study, we excluded from our research and assessment comments related to companies with market capitalization greater than $2 billion on the dates of analysis, which were November 4 and 5, 2020.

Our analysis included comments filed on the SEC EDGAR database during the period from May 1, 2019, to April 30, 2020, which we'll refer to as 2019–2020.

Comments for the following SEC filings were considered:

S-1	10-K	10-Q	20-F

To achieve a fair and objective assessment of the data, we considered only the first instance of a SEC comment letter for an individual filing, given that, in subsequent instances, letters from the SEC often contained comments of similar nature to those found in the first iteration, or enhanced the previous comments if not appropriately addressed.

While the period of analysis under our current and previous reports, known as 2019–2020 and 2018–2019, respectively, was for 12 months, we nevertheless used a ratio-based methodology to generate comparable data across the years.

We considered cases when shifts in comment ratios in a subset of comments from 2018–2019 to 2019–2020 exceeded the mean variance in that subset to be significant variances over the last two years.

For example, out of the 1,126 comments directed toward S-1 filings in 2018–2019, 185 were related to R&D, amounting to a ratio of approximately 16.4%. The same ratio increased to roughly 21.1% in 2019–2020, an increase of approximately 4.7%. Because this was greater than the mean variance among other topics in S-1 filings over the stipulated time period, we considered the variance in R&D-related comments toward S-1 filings to be significant.

Finally, some of the comments in this report were edited in the interest of clarity and brevity. Identifiable information, such as the names of companies, products, places and dates, as well as dollar figures, were omitted in the SEC sample comment sections.

Overall Trends

In total, there were 799 SEC comments issued in response to Forms S-1, 10-K, 10-Q, and 20-F filings in 2019–2020, a substantial drop from 1,236 comments in 2018–2019.

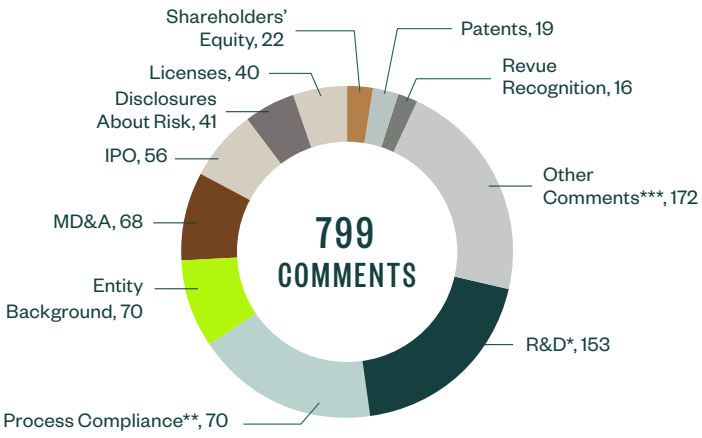
Comments this year were largely spread across several key categories, and those related to R&D were most prominent, garnering a 19.1% share. Much of the SEC's focus was based on understanding companies' results from ongoing clinical trials and studies, alongside their developmental pipelines and upcoming products.

Process compliance was the next major category at a share of 17.8%, with majority comments—as in the 2018–2019 study—requiring companies to make requisite disclosures throughout their prospectuses, including filing all material information.

This was followed by comments requiring disclosure on entity background, management's discussion and analysis (MD&A), and the actual offering, as well as any current or anticipated risks related to the business.

Information around licensing agreements, shareholders' equity, underlying patents, and revenue recognition collectively constituted another significant chunk of SEC scrutiny, followed by various other comments targeting firm-specific controls and regulatory features.

FIGURE 2: Overview of Process Compliance



R&D comments relate to clinical trials and studies, FDA filings and communication, product pipeline, products and services, and other highly firm-specific information.

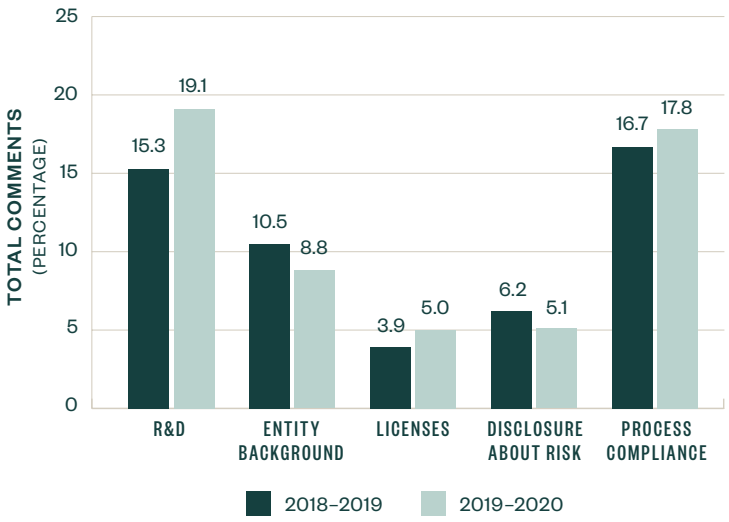
Comments related to process compliance tend to be more administrative and formulaic, but because of the sheer volume of such comments, companies have an opportunity to significantly reduce filing delays by understanding the nature of scrutiny under this topic and taking the appropriate steps to comply.

Other recurring comments include those related to emerging growth companies, controls and procedures, proxy disclosures and material contracts.

SIGNIFICANT SHIFTS

A number of topics saw a slight-to-significant shift in focus when compared to 2018–2019, with the positive or negative variance measured as a ratio to the total number of comments. This includes categories such as R&D, entity-related information, licensing agreements, risk-based disclosures, and process compliance.

FIGURE 3: Significant Shifts in SEC Focus for Overall Filings | *By Ratio of Comments*



Comments related to R&D saw an increase in focus by 3.8%, while those related to licenses and SEC reporting increased by 1.1%. Comments directed toward entity background and risk disclosure slightly declined by 1.7% and 1.1% respectively.

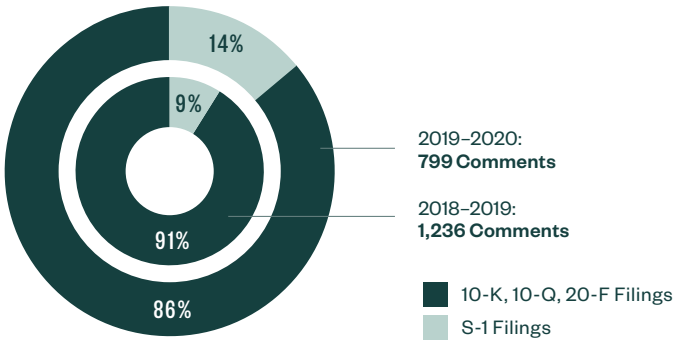
These shifts, however, were relatively marginal in size, highlighting that the nature and composition of comments over the last two years remained fairly consistent.

COMPOSITION BY FILING TYPE

Similar to 2018–2019, S-1 filings continued to lead in relation to SEC scrutiny. Of the total 799 comments analyzed in the study, roughly 86%—or 684 comments—were directed at S-1.

This is slightly down from a share of 91% in 2018–2019. The remaining 14% of comments were directed toward Forms 10-K, 10-Q, and 20-F filings.

FIGURE 4: Percentage of Comments | *By Filing Type*



In terms of categorization, the nature of comments continued to vary among pre- and post-IPO companies. Areas such as R&D, process compliance, entity background, risk disclosure, and details pertaining to the actual IPO transaction, remained very much dominant for S-1 registrants. Many were asked to elaborate on their product pipeline, solution breakthroughs, potential market standing and anticipatory risks, and clarify details of the actual offering.

Contrastingly, comments for Forms 10-K, 10-Q and 20-F filings were more performance-based and operational in nature.

This includes requiring companies add detail to MD&A, explain revenue recognition terms across various contracts and arrangements, and carry out requisite compliance checks across their filings. Meanwhile, some comments were rather technical, requesting adherence to internal control over financial reporting and having companies file all necessary certifications.

This trend was closely observed in the previous report as well.

NUMBER OF COMMENTS ISSUED

A key change from 2019–2020 was the number of comments under review. Total SEC comments directed toward all four filings—Forms S-1, 10-K, 10-Q, and 20-F—dropped by 35.4% from 2018–2019 to 2019–2020.

This fall can be attributed to various reasons. First, SEC comment letters for S-1 prospectuses had significantly fewer comments this time, even those pertaining to draft registration statements for the first iteration.

Second, many comment letters were directed toward other filings, such as S-3 and S-4, highlighting greater scrutiny on other filing types.

This may be reflective of both market dynamics as well as greater compliance by first-time IPO applicants, which limits the opportunity for further questions.

Trends in S-1 Filings

Despite a drop in the total number of comments, S-1 filings continued to claim most of the SEC's attention in comparison to other filing types, encapsulating over 684 comments in this year's review. This equates to a share of 86% of the 799 comments analyzed. This is slightly down from 2018–2019, when S-1 comments made up 91% of the mix.

FIGURE 5: SEC Categories for S-1 Filings

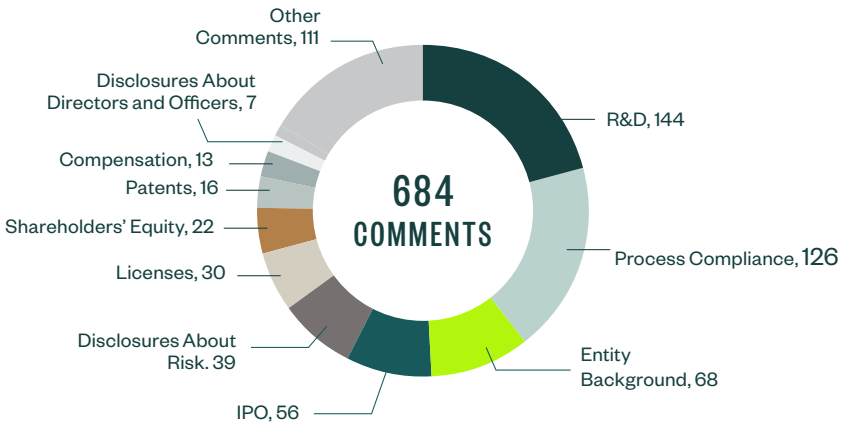
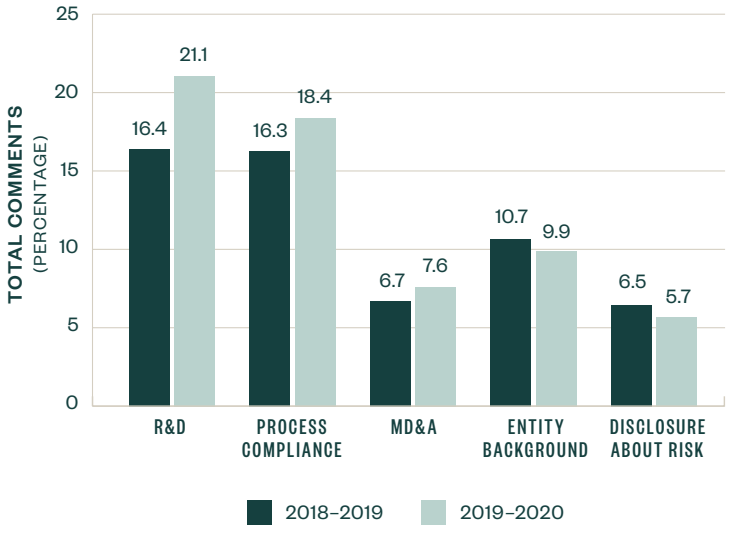


FIGURE 6: Significant Shifts in SEC Focus For S-1 Filings | *By Ratio of Comments*



In the comparative analysis, we noted significant shifts in some specific categories in the life sciences industry. Comments directed toward R&D went up by 4.7% in 2019–2020, while those related to SEC reporting and MD&A increased by 2.1% and 0.9% respectively.

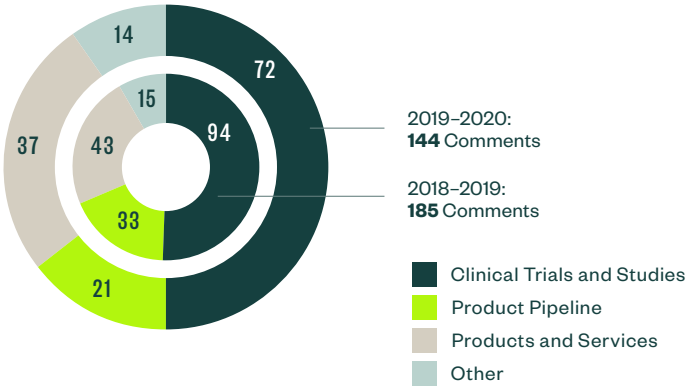
On the other hand, comments related to entity background and risk disclosure went down by 0.8%.

Apart from R&D and SEC reporting, many comment categories saw a variance of less than 1%. This highlights that the category composition mix remained largely consistent over the last two years, with certain salient topics continuing to attract greater SEC scrutiny.

These key topics are examined in further detail in the coming sections.

R&D

FIGURE 7: Number of Comments | *By Entity-Related Subcategory*



R&D sits at the fulcrum of the life sciences industry, bringing in creativity, innovation, and novel therapies each year. It's one of the most critical functions in the entire value spectrum, determining the depth and breadth of a company's product pipeline, market potential, competitive advantage, and operational sustainability.

In the advent of global disease outbreaks and emerging health concerns, the need for players to sustain and even ramp up R&D activities is pivotal.

Consequently, this category continues to attract substantial SEC scrutiny every year, especially for new registrants. Item 101 of Regulation S-K specifically requires registrants to describe their general business development and plan of operations that includes, among other elements:

- An explanation of material product R&D to be performed during the period covered in the plan
- Any anticipated material changes in number of employees in the various departments, such as R&D, production, sales, or administration

It's unsurprising that comments related to R&D made up the largest category in 2019–2020, constituting over 21% of total S-1 comments. This represents an increase in share by almost 4.7% from the previous report. Within this, information related to companies' clinical trials and studies, developmental product pipelines, and upcoming candidates were of the greatest importance. This was followed by a range of other diverse comments requiring information on FDA communications for commercialization of new drugs as well as costs undertaken to develop them.

Providing an accurate and objective representation of R&D activity is one of the most critical factors, with the SEC emphasizing the need to support all claims with concrete data. Inferences on new product performance must be cautiously made, with statements covering all possible implications.

CLINICAL TRIALS AND STUDIES

Similar to the previous report, the topic of clinical trials and studies stood out as the most dominant R&D subcategory in 2019–2020, with a total of 72 comments making up over 50% of the mix.

Much of the focus was placed upon requesting applicants expand their disclosure of both clinical and preclinical studies, giving details such as trial dates, duration, location, participant characteristics, dosage methodology, endpoints, and final results.

The SEC continued to emphasize the disclosure of all serious adverse events observed, requesting applicants provide the extent and frequency of these events in the patient population.

Reliance on external test results was another area of examination. Data that isn't based on head-to-head trials may not be directly comparable and should be removed or revised.

It's important to consider the entire clinical timeline. Adhering to regulatory requirements—such as carrying out human-factors studies, conducting additional tests with foreign subsidiary trials, or meeting specific drug designation standards—can create a longer R&D cycle.

Information sufficiency, clarity, and objectivity is the key takeaway. Companies must provide a sound picture of their trial testing methodology, including the transition from different phases. Using conclusive statements to describe trial results should be avoided, and all relevant claims should be based on actual data.

Sample Comments

> *We note your disclosure in the second paragraph of this section regarding the results of your preclinical trials of [product name]. Please limit the prospectus summary to a description of the endpoints of your clinical trials and whether they were met. To the extent that you do discuss preclinical trials in the prospectus summary, please avoid conclusory statements regarding the results of these studies, and disclose a summary of how the tests were conducted, the number of animal models used, the number of tests conducted, and the range of results observed in these tests.*

> *With reference to your disclosure on page 104, please revise your Summary to provide context to all efficacy performance claims where your clinical studies were not statistically powered for efficacy evaluations.*

> *We refer to your disclosures on pages 100–108 concerning numerous preclinical studies/models/assays. For each such study that you reference, please revise to include information about the nature, design and results of that work so that investors have a basis to assess the applicable observation that you present. Without limitation, your discussion should identify the type of cells and methods utilized in the referenced study. Your disclosure also should indicate whether the results were or were not statistically significant and you should include all p-values and n-values.*

> *We note that you conducted a series of in vitro experiments evaluating [product name], [product name], and [product name] with determinations of more favorable, comparable, or less favorable. Please provide context for these studies by providing the specific details and parameters of the studies from which this data was drawn, including endpoints, duration of treatment, comparison against placebo or standard treatment, metrics utilized, statistical significance, etc. Without this contextual information, it may be difficult for the reader to draw an accurate and balanced assessment of these favorable results. If you cannot provide this information, please remove these comparisons.*

DEVELOPMENTAL PRODUCT PIPELINE

The timing and execution of trials ultimately determines each candidate's progress and schedule toward commercialization. Putting this information together results in a company's developmental product pipeline, which provides investors with a time horizon on new product launches.

This area constituted 14.6% of total R&D comments in 2019–2020, slightly down from a 17.8% share witnessed in 2018–2019.

The nature of scrutiny was again centered upon pipeline tables, with registrants being requested to remove programs that were too early in the discovery phase. The table must only depict products that are material to the company and have a concrete, laid out development plan.

The usage of graphics is also important. Registrants must be careful about how they incorporate columns and arrows to depict the progress of each product, making sure each graphic represents a true and fair picture.

Details such as target indications and their addressable markets should be clearly stated, as well as the status of ongoing regulatory approvals.

Sample Comments

> *Please shorten the arrows in your pipeline table to more precisely indicate the development status of each product candidate. As one example, we note that you are planning to conduct several additional preclinical studies prior to submitting an IND and initiating a Phase I trial for [product name] in 2022, yet the arrow indicates that you have completed preclinical studies.*

> *Your pipeline table appears to include every in-house development program. Please revise the table to include only those programs that are material to the company. If you believe that every program listed is material, please provide us with an analysis explaining your belief. In particular, to the extent your lead optimization program is material to the company, please discuss this in your analysis.*

> *Please refer to the "Discovery," "Optimization" and "IND-enabling" columns. Please advise how "IND-enabling" differs from pre-clinical. Additionally, please advise what is the difference between "Discovery" and "Optimization." To the extent you retain these columns rather than just "Discovery" and "Pre-Clinical" columns, please add detailed footnotes to the table to explain each development phase clearly so that investors can appreciate the differences between the phases.*

PRODUCT-SPECIFIC INFORMATION

While the pipeline table gives a holistic presentation of upcoming products, registrants are also required to make detailed disclosure concerning each developmental candidate. This includes providing information around key value chain drivers—whether it be obtaining all necessary approvals for the new drug in the target market, carrying out feasibility plans, or evaluating novel features of the product.

This topic attracted 25.7% of total R&D comments in 2019–2020, maintaining its significance from 2018–2019.

The description "balanced disclosure" is most suitable when it comes to describing new products. The SEC continued to emphasize registrants to disclose the benefits and challenges related to development and commercialization of each candidate and give the basis for all of these claims. Similar to clinical trials and studies, statements comparing a new product to other products and treatments in the market should be restricted, given that these observations aren't based on head-to-head trial data.

Meanwhile, the need to make sound disclosure on each product's target indication, clinical cycle, regulatory communication, and third-party collaboration also remained at the forefront.

Sample Comments

> *We note in your statements that you have identified more than [number] antibodies and believe you will be able to exploit them to develop product candidates. Please balance these statements here and in the Business section by providing more context about the potential for development of these antibodies, the extent to which you have actually engaged in development activities with any of them, and the challenges associated with developing them into product candidates. In addition, please discuss how you will or plan to go about allocating your resources among the development candidates.*

> *To the extent comparisons are not based on head-to-head trials, please revise here and throughout to remove statements that compare your drug candidate to other drug candidates, products, and treatments. For example, we note your disclosure on page 1 that [product name] is the first and only therapy to demonstrate statistically significant improvements in both signs and symptoms of DED in a single registrational clinical trial and your disclosure on page 86 that [product name] is the only therapy to demonstrate rapid onset of action to significantly improved signs and symptoms of DED.*

> *With reference to your disclosure in the penultimate paragraph on page 90, please revise the Business section to explain the favorable stability properties that [product name] dry powder formulation has demonstrated.*

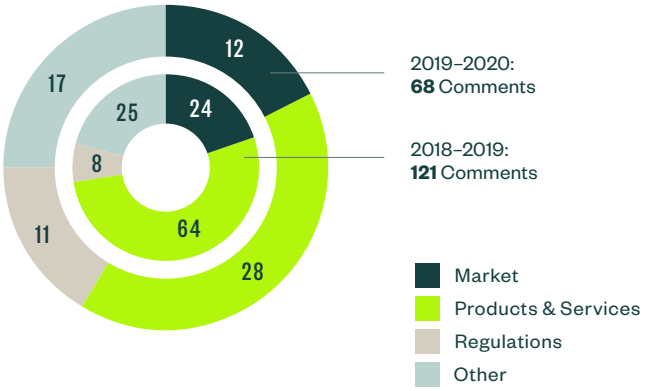
ENTITY-RELATED INFORMATION

The SEC clearly stipulates the importance of disclosing information about related persons, promoters and certain control persons in a transparent and accountable manner, which is required by Item 404 of Regulation S-K.

Though comments targeted specifically toward related parties dipped to less than 2% of total entity-related comments in the previous report, they later rebounded to 8% of total comments. Combined comments directed at related parties and related-party transactions added up to more than 13% of total entity-related comments.

Applicants are encouraged to be highly precise when it comes to explaining the relationship behind each and every connected party, and linking them with any subsequent transactions and dealings.

FIGURE 8: Number of Comments for S-1 | *By Entity Related Subcategory*



Disclosure on entity background has consistently been a key area of examination, especially for companies going public for the first time. Investors need to know an organization's ecosystem, business model, and operational framework to understand the context behind all information discussed in the prospectus.

Accordingly, the SEC requires registrants give a clear overview of their entity in the beginning of the statement before they delve deeper into specific risk factors or operating business activities.

The scope of disclosure for entity background largely includes details on a company's external environment—competitive landscape, market potential, and size—its products and services portfolio, organizational structure, regulatory ambit, and collaborative arrangements with related parties and third parties. It also involves highlighting any key stakeholders involved in the value chain that can ultimately affect the upcoming product pipeline and future performance.

Scrutiny of entity-related information comprised roughly 9.9% of total S-1 comments in 2019–2020, which is slightly down from a share of 10.7% in 2018–2019. Within this, comments related to current products and services and the external environment continued to claim much of the attention, while those related to regulations saw a substantial rise from last year.

PRODUCTS AND SERVICES

Comments related to companies' existing products and services portfolio constituted 41.2% of total entity background comments in 2019–2020, which is considerably down from a 52.9% share witnessed in 2018–2019. This area, however, continued to remain dominant out of all other subcategories.

The SEC emphasized the need for registrants to make balanced disclosure when describing their current operations, which includes disclosing both the benefits and drawbacks associated with the current product mix. Similar to R&D, companies must be cautious when making inferences about their products based on the performance of others in the market, given that these comparisons may not be based on head-to-head trial data.

Further, details on procurement, manufacturing arrangements, distribution channels, intellectual property rights, and any major revenue-accounting customer(s) must be clearly stated when registrants provide insight into their history and present-day standing.

As the crux of this disclosure lies in providing investors with an objective depiction of entity operations, using superfluous statements and words, such as best-in-class or first-in-class, must be largely avoided unless there's any concrete evidence to support the claim.

Sample Comments

> *Please balance your statement that you believe you have the first genetic medicine with the potential to significantly reduce the occurrence of seizures for Dravet syndrome patients and to address the severe intellectual and developmental disabilities of the disease by clarifying here that you are in an early stage of your development and that to date you have only conducted preclinical studies for your product candidate.*

> *You state that you are well-positioned to deliver on your mission of developing therapies for patients suffering from debilitating liver diseases. Please balance your disclosure by explaining that you have not yet completed a clinical trial as a company, and also that you do not currently have the necessary internal research and development capabilities, as you explain on pages 10 and 29.*

> *Please revise your filing to clarify your current business operations, including the products you currently manufacture and/or sell, as opposed to business activities planned for the future but not yet in effect. With respect to planned business activities, please discuss in more detail your plan of operation for the next twelve months, indicating the timing, material costs, and source of funds for such plans. For example, please describe the current status of the [project name] plan and expected timeline for its development, including any related costs to you. To the extent you are not engaged in a particular line of business, please eliminate any potentially unclear inferences to such business and operations. In this regard, we note you include disclosure regarding your medical device company.*

EXTERNAL ENVIRONMENT

Amid rapid advancement and dynamic regulatory oversight, coupled with sporadic, unpredictable events, giving an accurate representation of the external environment is critical.

Estimates of current industry standing and future market positioning must be clear and accurate to the best extent possible, especially for pharmaceutical preparation players targeting a niche but underserved population.

Accordingly, market-related comments made up 17.6% of all entity-related comments in 2019–2020, marking a slight decrease from a 19.8% share in 2018–2019.

Similar to the previous report, the SEC continued to challenge claims registrants made on their competitive landscape and competitive standing, asking them to provide further details on the market size, conditions, and steps needed for commercialization. This includes highlighting any specific hurdles a company may face when trying to get its drug out in a particular market.

Companies were also asked to provide the basis for any market calculations or statistics and disclose whether they commissioned any third-party data included in the statement.

Sample Comments

> *We refer to the disclosure in the second paragraph regarding the number of people who live with disabling hearing loss. Please include disclosure regarding the market size for individuals suffering from the type of hearing loss that can be treated with your lead product candidate, [product name]. Please provide similar disclosure on page 96 where you discuss the estimated annual costs associated with hearing loss.*

> *We note your statement in the second sentence of the first paragraph that your approach differs from traditional oncology drug discovery approaches. Please revise your disclosure here and in the Business section to explain in greater detail how your approach is different and why you believe that difference is a competitive advantage for your business. In addition, please tell us whether, to your knowledge, other companies are pursuing drug discovery approaches that are similar to or the same as your approach.*

> *Please explain clearly each material step you must take to reach commercialization of your technology to address the markets mentioned on page 26. Include the material hurdles before you are able to address these markets. If such detail is not appropriate for your prospectus summary, carefully consider the information that is the most significant, and briefly highlight that information in the summary and include more detailed disclosure elsewhere in your prospectus.*

REGULATIONS

Focus on regulatory issues substantially increased by almost 40% from the previous report, constituting 16.2% of total entity-related comments in 2019–2020.

Registrants were required to provide greater detail on how their products will meet all requisite regulatory approvals, which includes giving an overview of the approval process itself.

They were also asked to discuss their plans to enter foreign markets, if any, describing the steps they have taken to obtain the necessary regulatory and patent approvals.

Sample Comments

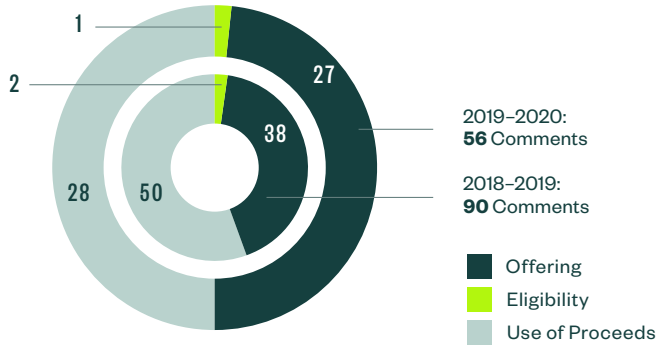
> *We note your disclosure that you anticipate that your proposed product will require the PMA approval process. Please more fully disclose the nature of that process; include, as applicable, the investigational device exemption process, and, if needed, whether you have received the exemption. Also disclose the duration of the PMA process, and clarify the nature of the "more rigorous examination" that you mention in the first sentence on page 29.*

> *Please expand the disclosure on page 33 to more fully describe the FDA approval process and the nature of regulatory oversight. For example, include in your disclosure the duration of the process, post-market reporting and record keeping requirements and remedies for noncompliance.*

> *We note that there are references to foreign regulators and foreign markets throughout the Risk Factors and other sections of your prospectus. Please revise to explain what non-US markets, if any, you plan to enter, and what steps you have taken to attain the necessary regulatory and patent approvals.*

IPO-RELATED DISCLOSURES

FIGURE 9: Number of Comments for S-1 | *By Initial Public Offering-Related Subcategory*



Focus on IPO-related disclosures accounted for roughly 8.2% of total S-1 comments in 2019–2020, similar to the 8% share witnessed in 2018–2019. The IPO category consists of the following three subcategories:

1. Offerings
2. Use of proceeds
3. Eligibility

Within these subcategories, SEC comments centered on a company's offering terms, cover page, securities, price, structure, use of proceeds, or eligibility.

The SEC continued to emphasize greater disclosure and clarity in the prospectus, mainly coming from Items 501 and 504 of Regulation S-K, as well as compliance with rules and regulations under the Securities Act. This includes detail on topics such as the offering price, structure, and underlying conditions, alongside providing a concrete plan on the use of proceeds.

On a generic level, comments in this category remain procedural year-over-year, with the SEC requiring clear-cut disclosure in the cover page and prospectus summary with regards to key aspects of the offering. The aim is to provide investors with unambiguous disclosure on exactly how the registrant is placing the offering and how it will be utilized to further its intended business objectives.

OFFERING

Comments related to the actual offering constituted over 48% of total IPO-related comments in 2019–2020, marking a slight increase from a 42% share in the previous report.

Registrants were asked to make both mechanical and factual disclosures. This included the following disclosures, among others:

- Describing factors considered when determining the offering price
- Modifying the fee table to reflect the amount of securities being offered and their price
- Disclosing the offer termination date

- Clarifying underwriting arrangements and the activities of selling shareholders, in relation to the offering

The SEC further required companies having shares quoted on the OTC Pink Market to disclose a fixed price at which their shares will be sold until the time they are listed on a national securities exchange or quoted on the OTC Bulletin Board, OTCQX, or OTCQB.

Sample Comments

> *We note your disclosure that no assurance can be given that your application to list your common stock on the NYSE American will be approved. With reference to your disclosure on page 60 that you will not consummate this offering if your common stock is not approved for listing on the NYSE American, please clarify your disclosure to state whether the listing of your common stock on the NYSE American is a condition to this offering.*

> *We note your disclosure that your common stock is currently quoted on the OTC Pink. Please confirm your understanding that being quoted on the OTC Pink does not satisfy the requirement that there be an established public trading market with respect to secondary at-the-market offerings for purposes of identifying the offering price on the prospectus cover page as required by Item 501(b)(3) of Regulation S-K. Please revise to clarify that the selling shareholders will sell at a fixed price or within a bona fide price range until your shares are listed or quoted on an established public trading market and thereafter at prevailing market prices or privately negotiated prices.*

> *We note your amended disclosure indicating the offering is being made on a best-efforts basis. Please revise your cover page to include the date the offering will end. Additionally, disclose any arrangements to place funds in escrow, trust or similar account, and if you have not made any such arrangements, state this fact and describe the effect on investors. Refer to Item 501(b)(8)(iii) of Regulation S-K.*

USE OF PROCEEDS

Capital allocation is a cornerstone of capital utilization. Funds must be channeled toward their intended business goals in a systematic manner, so as to reduce waste and idle cash.

Consequently, comments related to the use of proceeds accounted for 50% of the IPO mix in 2019–2020, demonstrating a similar significance to 2018–2019. The majority of these comments required companies to make additional disclosure as per Instruction 3 of Item 504.

Similar to prior years, the SEC required registrants to clearly outline how they'll use the proceeds raised from the offering to meet their specified purposes, quantifying the breakup for each. They were also required to identify any other material funding needed to fulfill their desired purposes, stating the related sources and amounts.

Detail and precision are the key takeaways here. Companies must refrain from setting vague expectations and outcomes and instead provide a clear plan of action.

Sample Comments

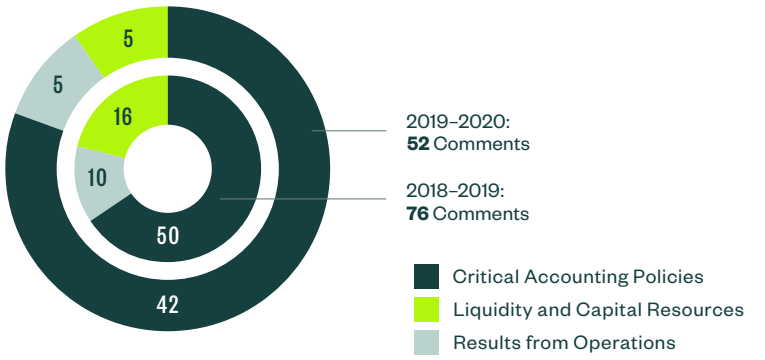
> *Please revise your disclosure in this section to indicate how far the proceeds from the offering will allow you to advance clinical development for [product name]. Please also disclose the second product candidate for which you intend to initiate clinical development. In addition, please specify the amount of capacity of the internal manufacturing capabilities you intend to establish with proceeds from the offering.*

Please expand your disclosure to specify the intended use of proceeds, including the amount you intend to allocate to [product name] and the other research and development activities, individually. Additionally, please revise to state how far the net proceeds are expected to allow you to continue in the development for each of your product candidates. Refer to Item 504 of Regulation S-K.

Please provide an estimate of how far in each of the proposed purposes you will be able to reach using the allocated proceeds from this offering, and disclose an estimate of the amount and sources of other funds needed if the anticipated proceeds will not be sufficient to fully fund all of the proposed purposes.

MANAGEMENT'S DISCUSSION AND ANALYSIS

FIGURE 10: Number of Comments for S-1 | *By Management's Discussion and Analysis Subcategory*



While financial statements provide a numerical overview of organizational performance, it's also important to outline the reasoning and context behind those numbers. Item 303 of Regulation S-K specifically requires registrants to provide information in MD&A as to the financial condition and results from operations, which includes covering aspects such as liquidity, capital resources, operational results, off-balance sheet arrangements and contractual obligations.

The SEC's focus on MD&A constituted 7.6% of total S-1 comments in 2019–2020, which is an increase from a 6.7% share witnessed in the previous report.

A major objective of MD&A is to highlight facts and circumstances specific to the registrant that are impacting results, which includes commenting on the potential and variability of earnings and cash flow.

In addition to this, companies should include the methodology they use to report transactions, alongside all underlying assumptions. This discussion and analysis should help investors understand the meaning of financial results and gauge whether the past results are likely to be indicative of future performance.

CRITICAL ACCOUNTING POLICIES

Similar to 2018–2019, the SEC's focus on companies' critical accounting policies constituted the majority of MD&A comments, making up over 80% of the mix in 2019–2020.

Registrants were asked to outline their methods, assumptions, and estimates, underlying critical accounting measurements and how changes to the same would impact financial results. They were also asked to provide analysis supporting their accounting treatment for material collaboration agreements, convertible stock, classification of liabilities, and asset valuations.

A majority of the IPO applicants were asked to disclose differences between the fair value of their ordinary shares leading up to the IPO and the estimated offering price to clarify their accounting for equity issuances, cheap stock, and stock compensation.

Accounting Standard Codification (ASC) Topic 606, Revenue from Contracts with Customers, was another hot button area of focus, with the SEC requiring companies to clearly show their adoption of the new standard and make all requisite disclosures and adjustments.

Sample Comments

> *Please revise to include a discussion of critical accounting estimates that addresses the material implications of uncertainties associated with the methods, assumptions and estimates underlying your critical accounting measurements. Your disclosures should address estimates and assumptions that are material due to the levels of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change, and that have a material impact on financial condition or your operating performance. Refer to Regulation S-K, Item 303 and the Commission's Guidance Regarding Management Discussion and Analysis of Financial Condition and Results of Operations, Release 34-48960.*

> *Once you have an estimated offering price or range, please explain to us the reasons for any differences between the recent valuations of your common stock and the estimated offering price. This information will help facilitate our review of your accounting for equity issuance, including stock compensation and beneficial conversion features.*

> *Please disclose the significant assumptions used to estimate the value of your acquired in-process research and development assets or direct us to existing disclosures. Please disclose a sensitivity analysis that demonstrates how changes in the key assumptions used would impact your acquired in-process research and development asset and related expense estimate.*

RESULTS FROM OPERATIONS

In an absolute sense, comments related to operational results went down by roughly 70% from the previous report, constituting only 9.6% of total MD&A comments in 2019–2020.

Registrants were asked to provide a narrative disclosure explaining any significant changes in revenue and expenses over the periods presented, which includes assessing the impact of both internal processes and external demand.

It's worth noting that a change in the number of comments for a particular category shouldn't be construed as a reflection of its importance. A declining number of comments merely suggests companies may be taking better steps to cover all the aspects in their original filings, leaving little room for further scrutiny.

Sample Comments

> *Please address the following regarding your reported [percent amount] increase in annual revenue of [dollar amount] to [dollar amount] at December 31, 2018, pursuant to Item 303(a)(3)(iii) of Regulation S-K: Please revise your brief discussion to provide a quantified narrative explaining the extent to which this increase is the result of price increases versus volume increases.*

> *You disclose on page 42 that you have introduced several new products. Clearly identify the nature of the new products and the amount of revenue produced by the new products.*

> *Revise to provide a tabular breakdown of the amounts included in your Selling, General, and Administrative expenses, and more clearly explain the fluctuations during the periods presented.*

LIQUIDITY AND CAPITAL RESOURCES

Comments related to liquidity and capital resources declined considerably from the previous report, making up 9.6% of total MD&A comments in 2019–2020.

Registrants were asked to comment upon their sufficiency of funds for operations, especially if they had significant debt and were in default. Material assets used as collateral must be disclosed, alongside its impact on capital resources.

As outlined in Item 303, the focus here for companies is to explain to investors any events or uncertainties that can affect their liquidity, indicating any material deficiency and the potential course of action to be undertaken.

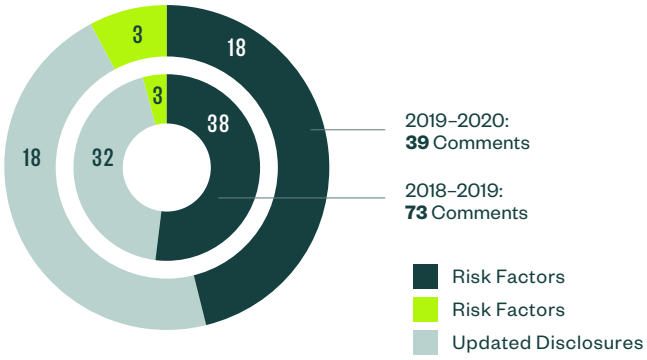
Sample Comments

> *Please expand your disclosures to describe the course of action you have taken or anticipate taking as it relates to the various promissory notes and related party notes payable that are currently in default as of December 31, 2018. In that regard, we understand that the Company anticipates using some of the proceeds from the offering to repay [dollar amount] of five promissory notes currently outstanding. It appears, however, that even with paying off such notes, there will continue to remain amounts that are currently in default. As such, please ensure your expanded disclosures highlight the potential consequences of continued default and the constraints it may have on your future liquidity and operating prospects, your ability to obtain additional financing and whether such continued default may cause you to have to revise the amounts that could be dedicated to your continued research and development activities. Refer to Section 501.13 of the Financial Reporting Codification.*

> *We note that you were in default under the terms of convertible promissory notes issued in 2015 and 2016 along with a promissory note issued in 2018. Describe the steps you are taking to address these defaults and explain the reasonably likely impact on your financial condition and operating performance. See section IV.C. of SEC Release No. 33-8350 for additional guidance.*

RISK DISCLOSURES

FIGURE 11: Number of Comments for S-1 | *By Risk-Related Subcategory*



Giving a balanced disclosure that addresses both opportunities and risks is imperative for all public companies, regardless of their size and industry. The COVID-19 pandemic has emphasized that no one is immune when it comes to facing uncertainty. Businesses must be ready to adapt to a constant change in dynamics and understand the implications of change on all parts of the value spectrum.

In the life sciences industry, factors like constant innovation and obsolescence, technological advancement, access to capital, and intellectual property protection always keep businesses on their toes. Coupled with company-specific characteristics, such as a distinct business model, processes, financial support, and business standing, each organization will end up having its own portfolio of risks that can affect operations.

Accordingly, providing a detailed disclosure of all company-related risks is pivotal, helping investors make sound judgments as to business resilience and future viability.

On the regulatory front, while the discussion of risk factors was previously provisioned in Item 503c of Regulation S-K, this has been effectively relocated to Item 105 post-modernization amendments. Under the caption Risk Factors, companies are required to provide "a discussion of the material factors that make an investment in the registrant or offering speculative or risky."

The SEC continues to emphasize, as part of the principles-based approach, the discussion of only significant and not generic risks and encourages the disclosure to be precise and concise.

While comments related to risk-based disclosures saw a relative decline from the 2018–2019 share of 6.5% of total S-1 comments to 5.7% in 2019–2020, the significance of this category remained intact.

Companies were asked to elaborate upon possible risks arising across any part of the business that are inherently firm-specific. These risks can stem from the external environment or reside internally within the firm. Examples include risks driven by:

- **Product quality.** Performance in clinical trials, tolerability, and safety.
- **Regulatory restrictions.** Clinical holds, approval delays, and added scrutiny.
- **Intellectual property rights.** Licensing restrictions and march-in rights.

- **Management control.** Dilutive effects, voting power, and structural volatility.
- **Process orientation.** Internal controls and digital controls.
- **Material dependency.** On suppliers, customers, or other stakeholders.
- **Legal disruptions.** Current and potential.
- **Going concern.** Recurring losses affecting future operations.

In line with previous years, the nature of comments toward risk disclosure largely required registrants to either add, delete, or modify certain risk factors in the Risk Factors section or provide additional details—updated disclosures—pertaining to risks discussed across the statement.

Sample Comments

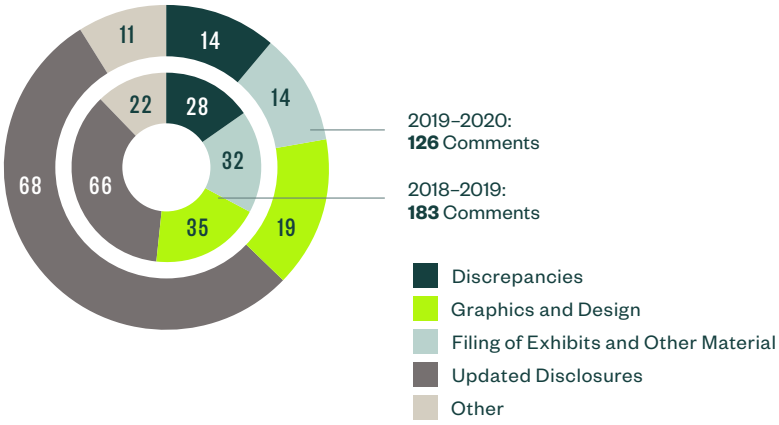
> *We note the disclosure on page 87 and elsewhere that you expect to incur significant and increasing losses until regulatory approval is granted for your lead product candidate, that regulatory approval is not guaranteed and may never be obtained, and that these conditions raise substantial doubt about your ability to continue as a going concern. Please revise your Summary to summarize the doubts about your ability to continue as a going concern. Also expand your Risk Factors to specifically address the associated risks.*

> *You state that you make extensive use of cloud-based storage systems and that you experienced a breach of one such system in [date]. Although you explain that the breach did not result in permanent loss of data, please expand your disclosure, here or elsewhere, as appropriate, to discuss the magnitude of the incident and its consequences, as well as remediation steps you have taken.*

> *We note that you may be subject to federal regulations such as march-in rights. Please provide additional disclosure regarding: the technology or technologies subject to march-in rights, the portion of your business that would be affected by the exercise of march-in rights, and whether and how you may be compensated in the event such rights are exercised.*

PROCESS COMPLIANCE

FIGURE 12: Number of Comments for S-1 | *By SEC Reporting Subcaegory*



Meeting compliance requirements is a key parameter for any business. The topic of process compliance is inevitably important for S-1 applicants, which are going public for the first time. Even though comments here are generally formulaic in nature, they do consist of a sizeable volume of comments every year. Accordingly, companies shouldn't overlook the importance of process requirements of the SEC, which can become a cause for filing delays.

Much of the SEC's review for draft registration statements goes toward having registrants make the necessary additions and modifications through their prospectuses and meet procedural standards.

While changes to Items 101, 103, and 105 of Regulation S-K present the most significant amendments in over 30 years, more of these updates are expected in the future as the SEC continues to emphasize a principles-based, registrant-specific disclosure. This may require reporting companies to invest additional time in the short run, to become familiar with the new requirements and to modify their standard disclosures accordingly. This area is expected to continue to attract significant SEC scrutiny in the future.

In 2019–2020, comments related to process compliance made up 18.4% of total S-1 comments, which is a slight increase from a share of 16.3% in 2018–2019. While a number of areas were examined within this larger sphere—comprising both procedural adherence, such as incorporation of certifications and relevant signatures as well as information verification—comments related to correcting discrepancies, filing of exhibits and graphic design, and making updated disclosures, remained at the forefront.

DISCREPANCIES

On a relative scale, while comments related to discrepancies consisted 11.1% of the process compliance mix in 2019–2020, sliding down from a share of 15.3% in 2018–2019, this topic continued to remain of considerable importance.

As simple as it may sound, the scope for discrepancies in registration statements can be quite large given the length and breadth of a typical prospectus. Companies are required to make varying disclosures in different sections of the document, which can lead to inconsistent facts, figures, or opinions in a range of areas.

Many comments in 2019–2020 were focused on discrepancies arising in companies' share capital, with conflicting numbers provided in different parts of the statement. Meanwhile, inconsistencies regarding specific facts on operational performance, product portfolio, and collaborative arrangements were also present, with the SEC requiring all disclosures to be in sound agreement.

Sample Comments

> *Your discussion regarding your [agreement name] on page 72 differs from that disclosed on pages 113 and F-14 with respect to the number of agreements entered into and the associated milestone payments. Please revise to correct this apparent inconsistency.*

> *It appears that you are registering [specific amount] shares of common stock to be offered by selling shareholders pursuant to the registration fee table. However, the prospectus and legal opinion indicate that you are registering [different amount] shares of common stock to be offered by selling shareholders. Please revise as appropriate to reconcile this discrepancy.*

> *We note the statement in this section that management is endeavoring to commence revenue-generating operations, which appears inconsistent with the reported results in the financial statements. Please reconcile.*

FILING OF EXHIBITS AND GRAPHIC DESIGN

Focus on filing requisite exhibit material and taking care of graphics and design together made up 26.2% of total process compliance comments in 2019–2020. While this share considerably went down from being 36.6% in 2018–2019, the significance of these two categories remained intact.

Comments here were highly procedural in nature, having companies comply with all exhibit guidelines as stipulated in Item 601 of Regulation S-K. This section lists all documents that need to be filed with the S-1, in addition to those that may be incorporated by reference. These include acquisition and reorganization plans, articles of incorporation, contractual arrangements, expert opinions and consents, among others.

Materiality is the key word when it comes to creating the exhibit index. Registrants must file documents pertaining to all material agreements or otherwise provide an analysis of why they believe certain arrangements aren't material enough to be filed separately.

In addition, companies must provide proofs of all graphics used in the prospectus, giving further disclosure, if required, to the SEC.

Sample Comments

> *We note the disclosure that you rely on contractual arrangements with [entity name], a consolidated variable interest entity, for your CBD-related operations. Please file the relevant contracts for these contractual arrangements as exhibits to this filing, or advise.*

> *Please provide us proofs of all graphic, visual, or photographic information you will provide in the printed prospectus prior to its use, for example, in a preliminary prospectus. Please note that we may have comments regarding this material.*

> *We note that the prospectus includes information from a commissioned study. Please identify the party who prepared the study and revise the exhibit index to indicate that you will file a consent from such party pursuant to Rule 436 of the Securities Act.*

UPDATED DISCLOSURES

Similar to the previous report, a considerable number of process compliance comments were directed at the broad-based subcategory of updated disclosures, which not only requires registrants to update information throughout the prospectus but also provide greater clarity in certain areas.

This area attracted over 68 comments in 2019–2020, equating to over 54% of the process compliance mix. This marks a substantial increase from a share of 36.1% witnessed in 2018–2019.

The nature of disclosure was quite wide, asking companies to make revisions such as:

- Update their financial statements
- Clarify developmental and reporting assumptions
- Give reasoning for compliance-related claims
- Provide greater detail regarding private placements, underwriters, and prospectus amendments

Within this, a key area of focus was on exclusive forum provisions. Companies were asked to clarify whether the provision applies to actions arising under the Securities Act or Exchange Act and state this clearly in the prospectus. It's vital to provide the scope of this action and its enforceability on potential claims.

Given the nature of this section, which looks over information provided throughout the prospectus, SEC scrutiny is expected to continue. The most important consideration for registrants would be to keep information as clear and up to date as possible to prevent recurring revisions.

Sample Comments

> *We note the financial statements included in the draft registration statement are as of a date 135 days or more before the date the document was submitted. Based on your representation that, at the time of the contemplated offering, you will be required to present the March 31, 2019, interim financial statements in the document, please update your disclosure to include these financial statements. We will not perform a detailed examination of the draft registration statement until you do so.*

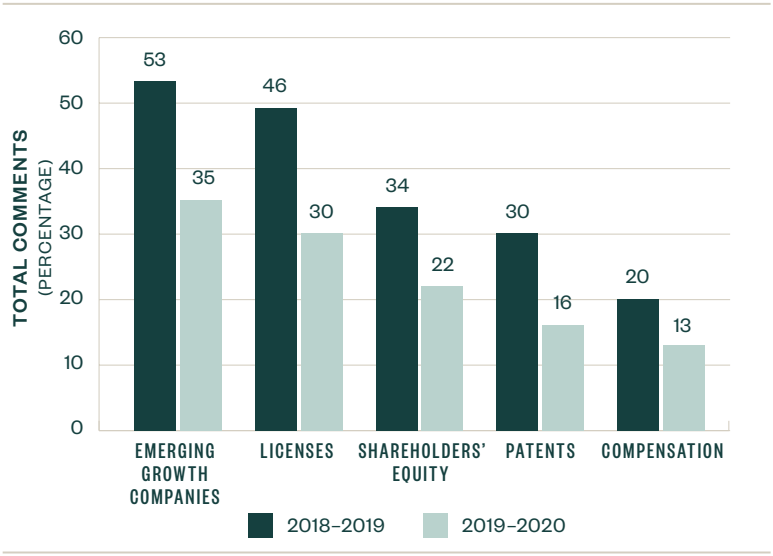
> *We note your disclosure here and on page 171 that your certificate of incorporation will contain an exclusive forum provision. Please disclose whether this provision applies to actions arising under the Securities Act or Exchange Act. If these provisions do not apply to actions arising under the Securities Act or the Exchange Act, please ensure that the exclusive forum provision in the certificate of incorporation and your disclosure regarding the provision in the prospectus state this clearly. If the provision does apply to actions arising under the federal securities laws, please disclose that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. In addition, file a copy of your certificate of incorporation with your next amendment or tell us when you plan to do so. Note that we may have further comment after review of this document and your revised disclosure.*

> *We note that you have omitted substantially all of the disclosure required by Part I of Form S-1 in this post-effective amendment to your registration statement on Form S-1. Please amend to include all of the disclosures required by Part I. Refer to Rule 472(b) of the Securities Act of 1933, as amended.*

> *Please revise your disclosure on pages 1–9 to avoid repetition of the detail that you include later in your prospectus. For example, we note that much of the disclosure in the tables and footnote on page 6 appear on page 104 in your prospectus.*

OTHER DISCLOSURE TOPICS

FIGURE 13: Number of Comments Related to Other Disclosure Topics for S-1



A wide range of other topics were covered in SEC comments directed at S-1 filings in 2019–2020, including comments related to the emerging-growth company status, licensing agreements, shareholders' equity, patents, and compensation. Together, these comprised over 17% of total S-1 comments.

EMERGING GROWTH COMPANIES

The 2012 Jumpstart Our Business Startups (JOBS) Act facilitated small businesses to go public under emerging-growth company (EGC) status. This status allows them, among others, to have less expansive disclosures than that required by non-EGC candidates and to defer compliance with certain accounting standards.

Typically, a company retains EGC status for the first five fiscal years of completing an IPO, unless one of the following occurs:

- Its total annual gross revenues are $1.07 billion or more
- It has issued more than $1 billion in nonconvertible debt in the past three years
- It becomes a large accelerated filer, as defined in the Exchange Act, Rule 12b-2

Comments related to EGCs constituted 5.1% of total S-1 comments in 2019–2020, registering a slight increase from 2018–2019. The SEC continued to ask registrants to provide copies of all written communications, as per Rule 405 of the Securities Act, and requested them to clarify their EGC status and elections.

Sample Comments

> *Please provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.*

> *You disclose that the JOBS Act provides the option for emerging growth companies to delay adopting certain accounting guidance. Please revise this section, as well as your disclosure about being an EGC elsewhere in your document, including page 7, to definitively confirm whether you have elected to avail yourself of this option. If you have elected to avail yourself of that delay, revise this risk factor to discuss the implications.*

LICENSES

With drug development being a highly capital-, knowledge-, and time-intensive process, the importance of collaboration remains steadfast. Players are increasingly entering into license agreements as a means of reducing product development costs, sharing risks, and capitalizing upon expertise.

The SEC's focus on licenses made up 4.4% of total S-1 comments in 2019–2020, maintaining its significance from 2018–2019.

Registrants were largely asked to give a thorough disclosure on the material terms of their license agreements, which include details on each party's rights and obligations, nature of intellectual property transferred, agreement duration, royalty range, termination circumstances, and payment provisions.

The focus here is information clarity. License agreements can be quite complex due to the nature of the arrangement or number of parties involved or payment structure. Providing a clear picture of all terms and conditions and their underlying implications is paramount.

Sample Comments

> *We note that you have licensed certain pending patents from [entity name]. Please amend your disclosure to discuss the material terms of this license agreement. In your description of this agreement, you should specifically identify, to the extent material: each party's rights and obligations; nature and scope of intellectual property transferred if the agreement involves a license; duration of agreement and royalty term, if applicable; termination provisions; and payment provisions. In addition, please file the agreement as an exhibit to your registration statement as required under Item 601(b)(10) of Regulation S-K.*

> *We note your disclosure that you may be entitled to double-digit royalties on any future product sales in the licensed territory. Please revise your description of royalty rates to provide a range that does not exceed ten percent.*

> *The disclosure of your accounting policy for revenue under collaborative arrangements on page F-11 suggests you may be eligible to receive additional milestone payments as well as the reimbursement of research and development expenses under your collaboration and license agreement with [entity name]. Please revise to disclose the total aggregate milestone payments you may become eligible to receive as well as a discussion of potential reimbursements of research and development expenses.*

SHAREHOLDERS' EQUITY

Companies are required to make a thorough disclosure on the nature and composition of their shareholders' equity, discussing any short- to long-term implications that can alter interest and control. This is a core pillar underpinning the overall capital structure, typically an area of intense investor focus.

Consequently, comments directed toward shareholders' equity captured roughly 3.2% of total S-1 comments in 2019–2020, in line with the previous report.

The SEC continued to ask registrants to clearly disclose beneficial ownership percentages, explain terms and rights governing each class of shares, and discuss the activities of selling shareholders, alongside touching upon any changes in valuation.

A key focal area in 2019–2020 was convertible preferred stock. Companies were asked to describe the terms and triggers of each type of conversion, provide its effect on common stock value and control, and highlight the extent of possible dilution.

Sample Comments

> *Please revise your prospectus summary to further describe your capital structure. For example please explain the conversion mechanism of your Series A Convertible Preferred Stock, the number of votes per share for that class of securities, the number of shares of voting common stock represented by that class of securities on an as converted basis, and what percentage of votes that may be cast this represents. Additionally, add a separate risk factor discussing these matters.*

> *Please insert a table showing the number and percentage of common shares acquired by existing shareholders and new investors and the consideration and percentage of consideration paid by existing shareholders and new investors, assuming 100% of the units offered are sold. Please refer to Item 506 of Regulation S-K.*

> *Please revise the column at the far right of your table to show shares beneficially owned and corresponding percentage upon completion of the offering, as opposed to "beneficially owned after maximum."*

PATENTS

With intellectual property being a bedrock for further innovation and development, the SEC continues to closely examine patent-related matters. Comments here comprised roughly 2.3% of the S-1 mix in 2019–2020, marking a very slight decline from the previous report.

Registrants were asked to describe their patent portfolios—both existing and pending—in greater detail, which includes disclosing the following:

- Specific products or technology to which each patent relates
- Whether the patent is owned or licensed
- Type of patent protection
- Patent expiration dates and expected expiration dates for pending applications
- Jurisdictions where patents have been issued or have pending applications

The SEC also requested companies, where necessary, to explain any material effects their patents or patent applications may have on the business, making sure to include requisite risk-based disclosures.

Sample Comments

> *Please expand your discussion of your licensed patent portfolio to disclose the types of patents you hold (i.e. composition of matter, use, or process) and the expiration or expected expiration date of your patents and patent applications.*

> *We note your disclosure that the last of three US patents are scheduled to expire in 2020. Please clarify the expiration date for each of these patents. Please also expand your disclosure to discuss whether you expect the expiration of these patents to have a material effect on your business, including any impact on future operations and the financial position of the company. Please add similar disclosure in the Summary and Risk Factors to discuss any potential material effect, to the extent applicable.*

> *Please revise to disclose the foreign jurisdictions in which you have issued or pending patent applications.*

COMPENSATION

The nature of compensation paid to executives and key employees is another critical area for disclosure, as stipulated in Item 402 of Regulation S-K.

Unlike the previous report, comments related to compensation emerged as a topic of mention this year, making up roughly 2% of total S-1 comments.

Registrants were asked to clearly present information pertaining to executive compensation in their summary compensation tables—as outlined in Item 402—and highlight any material factors necessary for a complete understanding.

In the case of share-based compensation, companies were asked to disclose the method used to estimate the fair value of equity instruments, in reference to ASC 718.

Sample Comments

> *Please disclose the post-termination compensation provision mentioned in section 5(c) of exhibit 10.4 and the change of control compensation mentioned in section 6 of that exhibit. Also, file as exhibits to your registration statement the agreements mentioned in the last sentence of this section.*

> *Please revise to disclose the method used to estimate the fair value of the equity instruments granted during the period to both employees and consultants, as well as the underlying basis for the assumptions used. Refer to ASC 718-10-50-2(f) and 505-50-50-1. In addition, as applicable, revise to provide the disclosures required by ASC 718-10-50- 2(c) through (e).*

> *Please revise your prospectus to provide a summary compensation table and a narrative description of any material factors necessary to an understanding of the information disclosed in the table. Refer to Items 402(n) and (o) of Regulation S-K. Please also include a table of outstanding equity awards at fiscal year-end. Refer to Item 402(p) of Regulation S-K.*

Trends in Forms 10-K, 10-Q, and 20-F Filings

Overall, comments directed toward forms 10-K, 10-Q, and 20-F comprised 14% of the total 799 comments analyzed in 2019–2020, marking a significant increase from a 9% share witnessed in 2018–2019.

Topics such as process compliance, MD&A, and revenue recognition continued to receive the greatest focus in comparison to other comment categories. These together made up 46 of the total 115 comments.

Examination of companies' licensing agreements and R&D activities stood next in line, which was followed by comments related to internal control over financial reporting.

Contrary to the nature of scrutiny for S-1, a greater focus was placed upon companies' operational activities, results, and internal controls, along with making sure they're making consistent disclosures across their filings.

FIGURE 14: Process Comment Categories for 10-K, 10-Q, and 20-F Filings | *2019-2020*

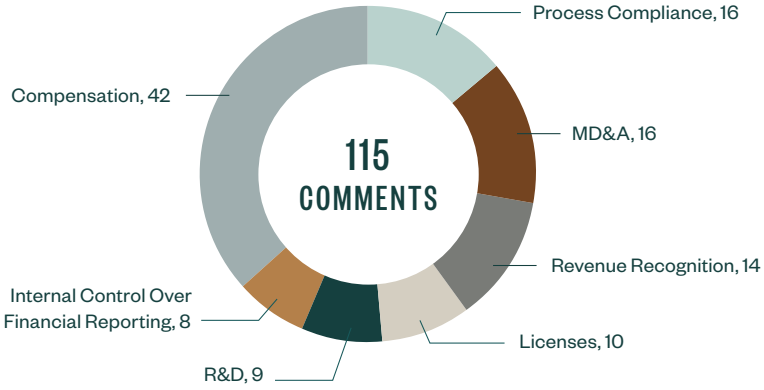
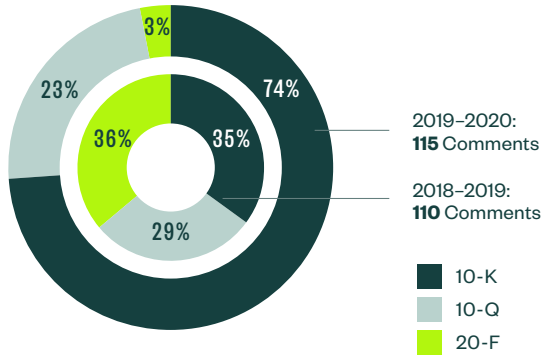


FIGURE 15: Breakdown of 10-K, 10-Q, and 20-F Comments | *By Filing Type*



Form 10-Ks attracted the greatest SEC scrutiny among all the three filings in 2019–2020, constituting 74% of the total 115 comments. This was followed by Form 10-Qs garnering 23% of the mix and Form 20-F having the remaining 3%.

FIGURE 16: Key Areas of SEC Focus for 10-K, 10-Q, and 20-F Filings | *By Number of Comments*

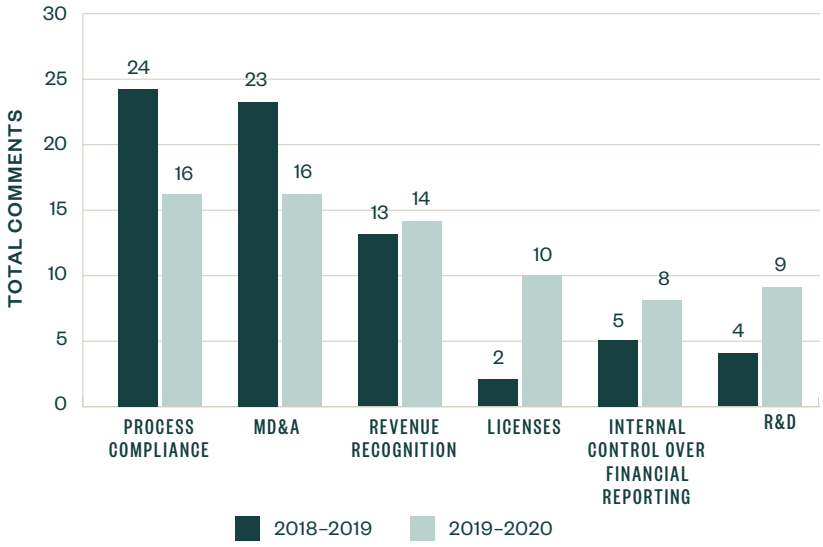
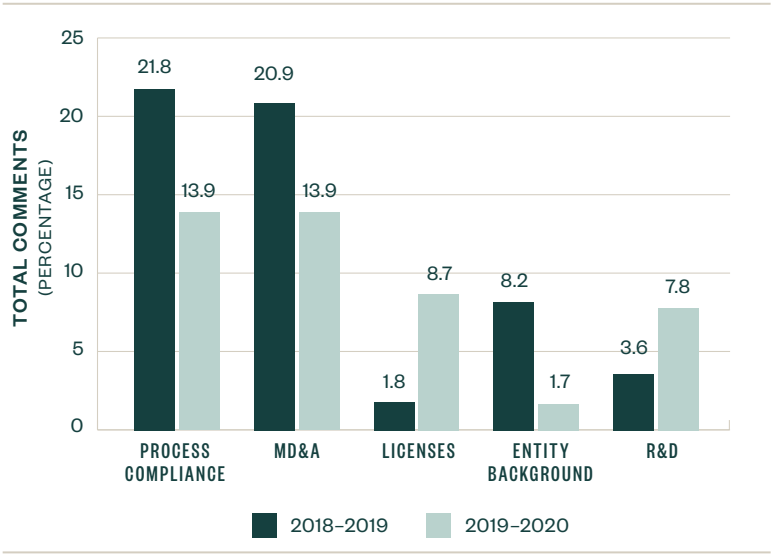


FIGURE 17: Significant Shifts in SEC Focus for 10-K, 10-Q, and 20-F Filings | *By Ratio of Comments*



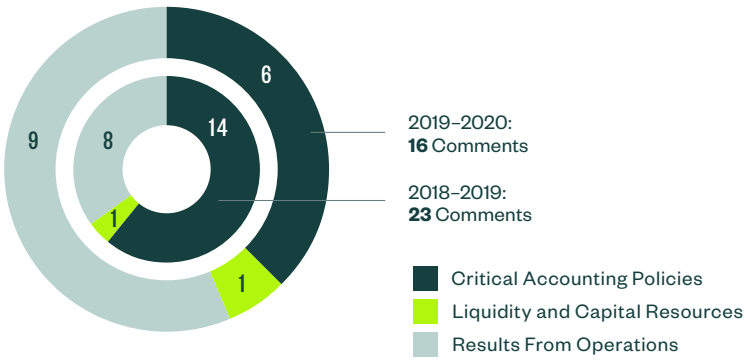
In comparison to 2018–2019, SEC scrutiny around licensing agreements and R&D significantly went up in 2019–2020, with the ratio of comments increasing by 6.9% and 4.2%, respectively.

On the other hand, comments directed toward process compliance, MD&A, and entity background decreased substantially by 7.9%, 7%, and 6.5%, respectively.

Nevertheless, these shifts shouldn't be construed as a reflection of what's important to cover in filings. For example, a drop in comments related to entity background doesn't mean there's a lesser need for disclosure on this subject. A declining number of comments merely suggests companies may be taking better steps to cover all needed aspects in their original filings, leaving little room for further scrutiny.

MANAGEMENT'S DISCUSSION AND ANALYSIS

FIGURE 18: Number of Comments Related to Other Disclosure Topics for S-1



Presentation and discussion of operational results has been a key area of SEC examination, for both pre- and post-IPO companies. As stipulated in Item 303 of Regulation S-K, registrants are required to present a detailed overview of their financial condition to investors and discuss any changes within, touching upon aspects such as liquidity, capital resources, results of operations, off-balance sheet arrangements, and contractual obligations.

While the share of comments related to MD&A decreased from being roughly 21% of total post-IPO comments in 2018–2019 to 14% in 2019–2020, this continued to remain a significant topic of scrutiny.

The SEC required companies provide a detailed discussion pertaining to material changes in operational results and present a quantified analysis of significant drivers. For example, when discussing changes in revenue for product sales, companies must attribute whether revenue fluctuations are due to changes in product volume or price and quantify the impact of both. Similarly, fluctuations due to new business activities—such as venturing into a new product range or acquiring new businesses—must also be explained, alongside any known trends or uncertainties in the external environment that may impact sales or income in the future.

Apart from financial results, the use of critical accounting estimates was another key area of focus. Companies were asked to provide their accounting methodology behind certain asset valuations and material agreements, citing the authoritative literature on which they relied. In addition, those using non-GAAP financial measures were asked to provide all reconciliations and disclosures pursuant to Item 10(e) of Regulation S-K.

On November 19, 2020, the SEC voted to adopt amendments to financial disclosure requirements as part of its modernization initiative, including those related to MD&A. These amendments restructure and simplify MD&A in line with a principles-based approach, reducing duplicative disclosure while enhancing the relevance of material information to investors.

With these developments in mind, the focus for registrants—is to be detailed, precise, and consistent in their discussion of operational results. It's imperative to understand the spirit and intent behind this ongoing simplification efforts, which is to make sure all key information is clearly and transparently communicated.

Sample Comments

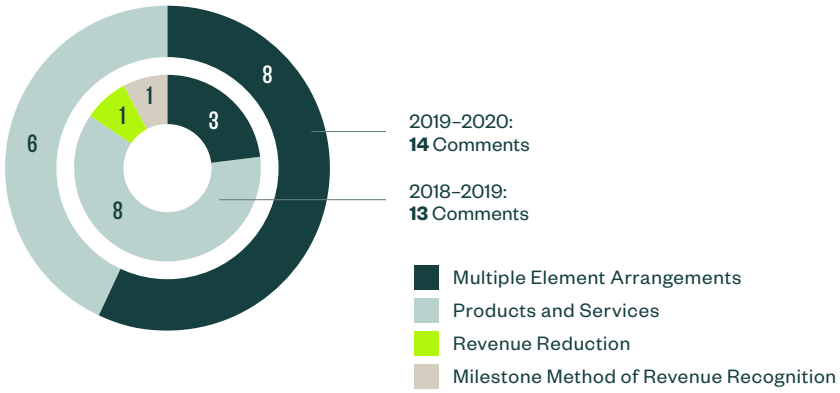
> *Please tell us the extent to which each change in revenue for product sales was due to volume versus price. Please explain your consideration of disclosing this information in your filing.*

> *Please tell us why you indicate that inventory valuation is a significant accounting estimate and why you include inventory as a critical accounting estimate on page 60 in MD&A when you do not appear to have inventories on your balance sheet and do not include a separate policy disclosure in Note 3. To the extent you have inventories through December 31, 2018, explain how they are utilized in providing your cell therapy technology services or cell banking storage.*

> *We note that you attributed the year-to-year fluctuations to the acquisition of [entity name]. In future filings, please expand your disclosure to provide investors with a more detailed description of significant components of revenues and expenses, including, but not limited to, both the existing and new business as well as any known trends or uncertainties that have had, or that you reasonably expect will have, a material favorable or unfavorable impact on net sales or revenues or income from continuing operations. In addition, when you attribute fluctuations to more than one item, you should quantify the impact of each significant item on the results of operations. Refer to Item 303(a)(3) of Regulation S-K and Section III.D of SEC Release No. 33-6835.*

REVENUE RECOGNITION

FIGURE 19: | *By Revenue Recognition Subcategory*



Revenue and the recognition of revenue remain critical pillars in financial reporting, especially within the complex nature of deliverables and timelines in the life sciences industry. The issuance of ASC 606, Revenue from Contracts with Customers, was intended to standardize key recognition policies and disclosures in this regard.

The core principle of Topic 606 is that an entity should recognize revenue when it transfers goods or services to a customer in an amount in which it expects to be entitled to receive from the customer.

Verifying sound transition and adherence to this new policy has become a key area of focus, attracting a significant amount of SEC scrutiny every year.

Consequently, comments related to revenue recognition comprised 12.2% of total post-IPO comments in 2019–2020, staying in line with the previous report.

Similar to 2018–2019, much of the focus was placed upon companies' multiple element arrangements, with many being asked to make the following disclosures as clear as possible:

- Identify the promised goods or services under the agreement
- Explain which promised goods and services are distinct performance obligations and which have been combined
- Quantify the total transaction price and explain how it's determined
- Disclose how the total transaction price is allocated among various performance obligations and the amounts that have been recognized over the year

The SEC required further information, on a case by case basis, pertaining to the receipt of any regulatory milestones or further commitments that may come to bear during the contractual term of an agreement.

Apart from this, companies were asked to clarify their application of ASC 606 across various fronts, which included both the estimation and presentation of different types of revenue.

Scrutiny related to revenue recognition—specifically ASC 606—is expected to continue, as companies', and the SEC's, interpretations of the standard align.

Sample Comments

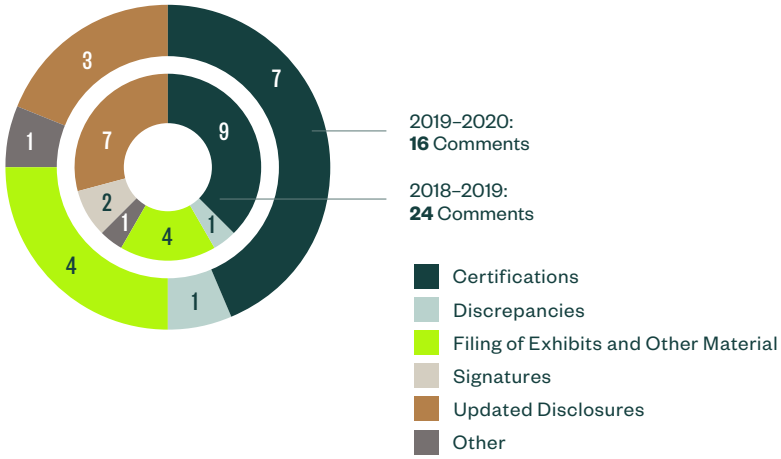
> *With respect to your [entity name] and [entity name] licensing agreements, please address the following: Identify for us the promised goods and/or services under the agreement. Tell us how you determined which promised goods and services were material and distinct, and thus performance obligations, as well as which promises may have been combined. Quantify for us the total transaction price, how it was determined, as well as the items (i.e. milestones, royalties, etc.) included or excluded and the reasons therefore, the amounts allocated to the various performance obligations, and the amounts recognized during the year ended December 31, 2018, and the three months ended March 31, 2019. Provide us a breakout of the regulatory milestones you may be eligible to receive by type and amount.*

> *You state that you do not recognize revenue until it can be reliably measured. Since IFRS 15 requires revenues to be recognized when an entity satisfies its performance obligation at the estimated transaction price, unless a significant reversal in the amount of cumulative revenue recognized is probable, please tell us how your accounting policy complies with IFRS 15. In addition, please clarify for us how you account for agreements which contain multiple performance obligations such as the [entity name] agreement.*

> *Please refer to the disclosure on Page 15 of your [date] letter that discusses your allocation of the transaction price and tell us the consideration you gave to allocating the transaction price to each of the material rights based on their standalone selling prices at contract inception. Refer us to the ASC 606 guidance upon which you relied to allocate the transaction price to each program using a relative fair value method and in turn allocation of the transaction price per program to each underlying performance obligation using the relative standalone selling price method.*

PROCESS COMPLIANCE

FIGURE 21: Number of Comments for 10-K, 10-Q, 20-F | *By Process Compliance Subcategory*



Despite a significant decline in the ratio of comments from the previous report, process compliance continued to be one of the greatest areas of scrutiny, capturing almost 14% of the post-IPO mix in 2019–2020. Similar to the S-1 category, while comments here are generally formulaic and administrative in nature, they do make up a sizable volume each year. The importance of this area can't be overlooked, as it may become a cause for further filing delays.

In terms of the nature of comments, much of the focus was placed upon certification-related compliance in 2019–2020, with the SEC requesting companies provide new certifications in relation to internal controls over financial reporting (ICFR), which conform with Item 601(b)(31) of Regulation S-K. This includes adopting the definition of ICFR as given in the Exchange Act and certifying adherence to all requisite obligations.

Filing of exhibits was another critical topic, with comments similar to those directed toward S-1 filers. Companies were asked to file all material contracts as part of their exhibit index or give an analysis supporting their determination otherwise.

Comments related to updated disclosures stood next in line, with the SEC requesting further detail and revision across various parts of the filing. This was followed by comments related to reconciling discrepancies or disclosing procedural information.

On a broader level, compliance has remained, and will remain, a key topic of focus for any type of company—pre- or post-IPO. Accordingly, SEC scrutiny can be expected to continue as companies reshape their practices to align with changing regulatory dynamics.

Sample Comments

> *You disclose a [date] license agreement with [entity name], whom you have disclosed on page 20 is a related party. It appears that a significant amount of your research and development activities may be derived from intellectual property included in this license agreement, including development activities that may be included in your [date] Letter of Intent or subsequent agreements with [entity name]. These agreements do not appear to have been filed as exhibits. Please confirm to us that you will file these agreements as exhibits, or provide your analysis demonstrating why you do not consider these agreements to be material contracts under Regulation S-K, Rule 601(b)(10).*

> *Please amend your filing to provide new certifications filed as Exhibits 31.1 and 31.2 to conform exactly to that provided in Item 601(b)(31) of Regulation S-K as it relates to internal controls over financial reporting (ICFR). In this regard, the introductory sentence in paragraph 4 should refer to ICFR as defined in the Exchange Act and certification 4(b) should discuss your obligations related to ICFR. Similarly, please amend the 10-Q for the quarterly period ended March 31, 2019.*

OTHER DISCLOSURE TOPICS

LICENSES

SEC scrutiny on licenses increased by 6.9% from the 2018–2019 report, comprising 8.7% of total Forms 10-K, 10-Q, and 20-F comments in 2019–2020.

Similar to previous years, the SEC required companies describe the material terms of their license agreements, which includes disclosing the product candidates associated with the license, aggregate amounts paid, royalty percentage, each party's obligations, and termination provisions.

Within this, the SEC specifically requested many to refrain from making vague disclosures on royalty amounts, such as, "ranging from high single-digit to low double-digit percentages," and disclose a royalty rate that doesn't exceed a 10-point range.

Sample Comments

> *We note your disclosure on page 5 that you entered into a license agreement with [entity name]. In future filings, please provide expanded disclosure to describe the material terms of the agreement, including:*
>
> - *The aggregate amounts paid to date*
> - *The royalty percentage or a reasonable range*
> - *Product candidates associated with the license*
> - *Each party's obligations*
> - *Contract term and termination provisions*

> *You state that [entity name] would pay you double-digit royalties on annual net sales of the assets, which may be subject to adjustment in specified circumstances. Please confirm in future filings you will disclose the royalty rate or a range that does not exceed a 10-point range.*

RESEARCH AND DEVELOPMENT

Comments related to R&D significantly increased from the 2018–2019 report (4.2%), making up 7.8% of the post-IPO mix in 2019–2020.

Similar to S-1 registrants, Forms 10-K, 10-Q, and 20-F filers were asked to provide greater disclosure in relation to their ongoing clinical trials and studies, making sure to disclose all serious adverse events observed. In addition to this, companies were requested to provide an analysis of their R&D expenses incurred each year, on a product-by-product basis.

Sample Comments

> *Your disclosure on page 3 states that in a Phase 2 clinical trial of [product name] conducted in [place], drug-related serious adverse events consisting of grade 4 neutropenia were observed in three patients and all recovered completely. It appears, however, based on your disclosure on page 76, that numerous other serious adverse events have been observed for [product name] as well as your three other product candidates. Please revise your future filings to disclose the frequency with which each type of serious adverse event occurred for each of your product candidates.*

> *Please provide us an analysis of research and development expenses incurred for each year presented by product candidate. Consider providing us proposed disclosure to be included in future periodic reports to improve your disclosure similar to your disclosure in the Form 10-K for the fiscal year ended December 31, 2015.*

MARKET CAPITALIZATION RANGE

The scope of this analysis focused on smaller companies with market capitalizations of less than $2 billion.

Over 62% of all Forms 10-K, 10-Q, and 20-F comments were centered on companies with a market capitalization of less than $500 million. Of the remaining companies, 23% were directed toward those with market capitalization between $500 million and $1 billion, while 15% pertained to those greater than $1 billion but less than $2 billion.

Smaller companies continue to attract the greatest scrutiny.

FIGURE 22: Breakdown of 10-K, 10-Q, and 20-F Comments | *By Market Capitalization Range*

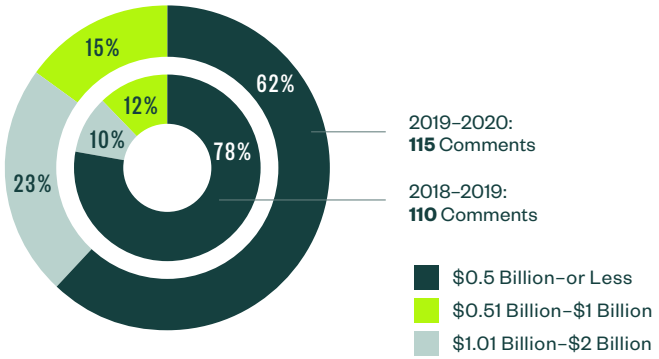
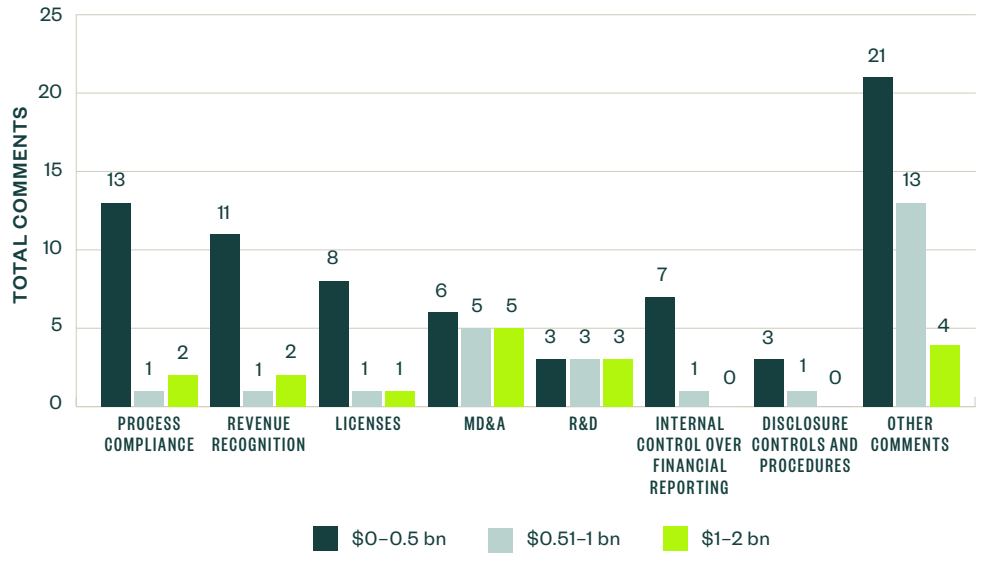


FIGURE 23: Trends in SEC Comment Categories by Market Capitalization 2019–2020 | *By Number of Comments*



Similar to previous years, company size and the extent of SEC scrutiny continue to have a negative correlation; the number of comments decreases as market capitalization increases. Companies that are new registrants may lack experience and expertise with SEC requirements and disclosures.

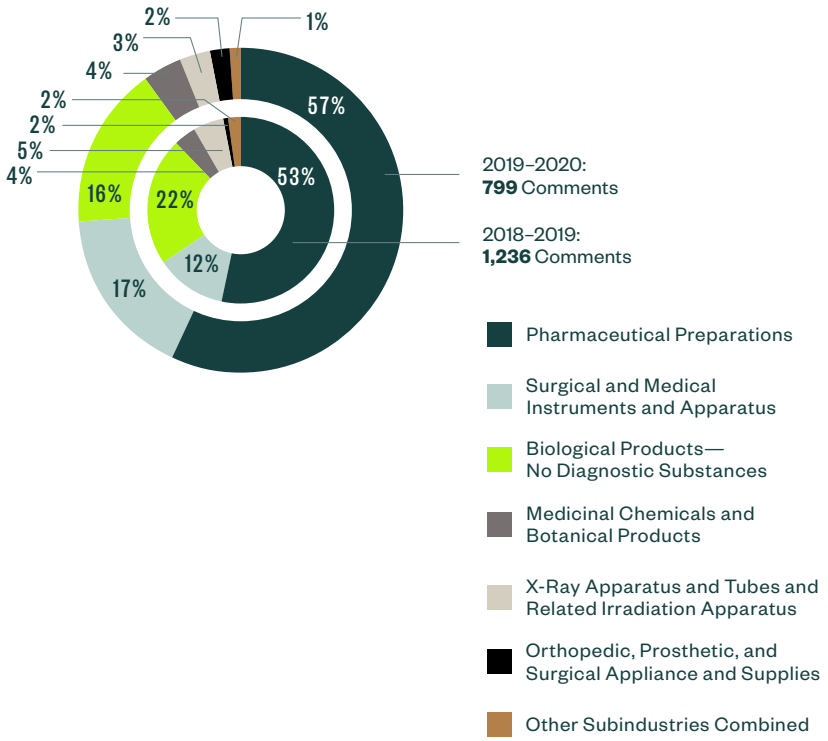
In other cases, smaller companies may have fewer resources to allocate to this effort, whereas larger capitalized companies may have greater resources, including more experience and in-house setups to help them maintain up-to-date compliance.

It's also worthwhile to note that the current market-cap distribution among life sciences companies indicates there may be a greater number of small-sized players than larger ones, which also impacts the distribution of SEC comments to each category.

Regardless of size, building a thorough understanding of the SEC's disclosure standards will help facilitate a smoother filing process for all companies.

SUBINDUSTRY TRENDS

FIGURE 24: Percentage of Comments | *By Subindustry*



Of all the subindustries analyzed in this study, pharmaceutical preparations continued to grab much of the SEC's focus. Its share of total comments further increased from 53% in 2018–2019 to 57% in 2019–2020. This isn't surprising because the majority of the Forms S-1,10-K, 10-Q, and 20-F filings studied in this analysis were from companies in pharmaceutical preparations.

Generically, companies in this subindustry are defined as primarily engaged in "manufacturing, fabricating, or processing drugs in pharmaceutical preparations for human or veterinary use." This includes a wide product portfolio that's largely intended for final consumption, including "ampoules, tablets, capsules, vials, ointments, medicinal powders, solutions, and suspensions."

Given this broad-based value spectrum, which consists of extensive clinical research, long product development periods, and complex intellectual property rights, the extent of compliance checks and disclosure required can be significant.

Surgical and medical instruments and apparatus stood as the next most significant subindustry, with a share of 17%, which was closely followed by biological products at 16%.

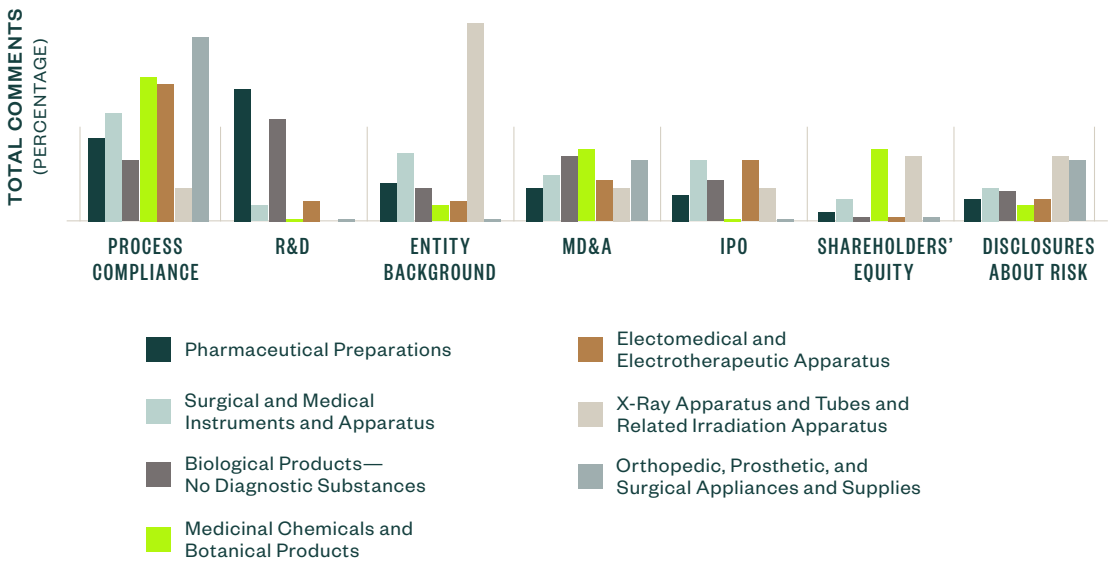
There's been an interesting shift of dynamics within these two categories, with the ratio of comments in surgical and medical instruments and apparatus increasing by roughly 5% from the previous report, while the ratio in biological products went down by more than 4%.

The composition breakdown of other subindustries was relatively small, each generally below 5%.

NATURE OF COMMENT CATEGORIES

While all subindustries are essentially part of the life sciences sector, they differ on an individual basis in their activities, corresponding value chains, and business models. This can make them subject to varied regulations and operational parameters, bringing in a slightly different SEC focus.

FIGURE 25: Share of Comment Categories 2019–2020 | *By Subindustry*



Compliance is an essential part of the life sciences industry. Consequently, comments related to process compliance remained significant across subindustries, generally making up between 20%–30% of the mix.

R&D continued to remain a significant area of scrutiny for companies in pharmaceutical preparations and biological products, due to developmental activities in this space. Meanwhile, entity-related disclosures were relatively more important for the subindustry x-ray apparatus and tubes and related irradiation apparatus, making up almost 50% of its total number of comments.

This doesn't mean, however, that the nature of comments within a subindustry remain static. Certain topics may attract greater scrutiny one year and less the year after. For example, companies in medicinal chemicals and botanical products saw much less focus on entity background and risk disclosures in the 2019–2020 report than the 2018–2019 report, while comments related to shareholders' equity greatly increased. Similarly, for surgical and medical instruments and apparatus, the number of comments directed toward IPO-related disclosures more than doubled over a year.

The key takeaway is that while there may be some topics that remain common for the entire sector, the nature of others will continue to vary among subindustries. Even within a subindustry, some categories may attract greater scrutiny in one particular year and backtrack the next. This depends on both market dynamics and timing, which may bring certain issues to the forefront and highlight efforts companies are taking to properly address these areas in their filings.

Companies need to stay abreast with the specificities of their own markets, paying close attention to any inherent challenges or sensitivities that may require additional clarification. They also need to keep a close tab on changing macro conditions on both a global and local level, understanding their effects on the business and whether that requires further disclosure. Information clarity and transparency will remain critical at all points during this process.

Conclusion

In the advent of global upheavals, new challenges, and unforeseen transformation, the need to adopt agile practices and stay abreast of ongoing developments has become paramount. Particularly in life sciences, players are faced with rising costs, intensive innovation pipelines, shorter product life cycles, and changing value spectrums.

They're also grappling with added pressures mounted by the COVID-19 pandemic. Time is short, stakes are high, and competition is intense as companies race to develop effective treatments and vaccines.

SEC COMPLIANCE TRACKER

Maintaining sound regulatory compliance is a cornerstone for driving up operational efficiency and reducing procedural delays.

A core part of maintaining compliance includes staying up to date with the SEC standards and requirements, which is applicable from the very first IPO registration statement to all subsequent filings required in the public domain. Companies can benefit from:

- Creating informative and sound documents
- Providing clear and adequate disclosures on all critical matters
- Keeping investor confidence intact

With IPO activity running strong in the life sciences domain as a host of new players go public, it's more important than ever to understand and adhere to filing guidelines.

It's always beneficial for companies to proactively identify particular areas of interest or focus in their filings that can attract SEC scrutiny beforehand, which generally varies according to company size, form and filing type, and the nature of operation.

This trend was observed in this 2019–2020 report, with the SEC seeking clarity from companies on a host of issues, ranging from making adequate disclosures and carrying out insightful discussions to providing a clear presentation of their information in filings.

POPULAR TOPICS

Similar to previous years, areas such as R&D and process compliance stood at the forefront. The SEC continued to request companies—especially first-time registrants—clearly explain their clinical trials and studies, giving a balanced disclosure of both favorable and unfavorable results observed.

IPO candidates were also asked to provide a thorough overview of their entity background in the beginning of their statements, which sets the context for detailed disclosures pertaining to business activities, anticipatory risks, material collaborations, and intellectual property in the latter part of the document.

Undertaking a thorough presentation, discussion, and analysis of operational results was a key area of focus, with companies being required to integrate all requisite standards and policies to account for transactions.

Adherence to Regulation S-K and Regulation S-X remained pivotal in the backdrop, for pre- and post-IPO players. This can be as simple as including the right signatures or filing the right documents.

WHY IT MATTERS

Knowing what's important—and why it's important—matters. Getting the process right the first time around saves both time and resources, enabling a smooth flow of operations.

This report aimed to familiarize life sciences companies with pertinent factors in their registration statements and filings, touching upon core SEC comments made in these areas. This applies to not only middle market companies included in the scope of this analysis, but also all other current and future registrants.

Insights from these generic trends, coupled with guidance from specialist advisors, can help companies anticipate and avoid impending obstacles. Preventing simple mistakes can in turn save much more time and money.

THE ROUTE TOWARD SEC FILING PREPARATION		
Familiarize yourself with the purposer of SEC filing and take note of designated forms	Understand your industry and requisite value chain of activities that need attention	Know where you fit in terms of the filing requirements and relevant procedures
Identify patterns in SEC comments, assessing those made for similar filings in the past	Analyze trends to understand and account for important salient features	Get in touch with specialist advisors to address doubts and receive customized solutions

WE'RE HERE TO HELP

To gain more insight into the SEC's comment process or questions on how to prepare your company for its IPO, contact a Moss Adams life sciences professional.

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- Medical devices
- Pharmaceuticals
- Digital health

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