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 is steadily rebounding after a two-year slowdown in 2015 and 2016.

PERFORMANCE RECAP

Over 160 IPOs raised a total of $35.5 billion in 2017, growing by 52.4% and 88.8%, respectively, from the previous year, according to the Renaissance Capital's US market review. This momentum carried into 2018, with the market registering the greatest quarterly proceeds and highest activity flow since 2016 within the first half of the year.

Subsequently, the third quarter of 2018 set a four-year record with 52 IPOs raising $11.2 billion, which brought the total count to a whopping 156. Offerings surged by 34% on average, with strong returns set forth by health care and technology.

Despite a somewhat lackluster performance in the fourth quarter that stemmed from a sluggish stock market and rising volatility, 2018 ended on a high note with a total of 190 IPOs accumulating $47 billion in proceeds. Biotech raised more money than ever with 10 IPOs garnering more than $1 billion, which put prospects high. In spite of some looming uncertainty, 2019 may become a mega year with many more filings being driven in.

LIFE SCIENCES ACTIVITY

A similar buzz in activity occurred in the life sciences industry, while it continues to grapple with ongoing patent expirations, generics, and biosimilars, encapsulated amid a pressing need to shift from volume to value-based solutions.

Technology

Meanwhile, technological accelerators rooted in software improvement and computing power also opened up new opportunities for researchers to leverage the human genome and develop innovative products. In fact, value driven by R&D creation in the United States reached an all-time high with aggregate sales of new products five years post-launch reaching $33.2 billion in 2017.

Drug Approvals

The number of drug approvals received by the Food and Drug Administration also surged by 104% in 2017 compared to 2016, reflecting an encouraging environment for new discoveries. This opened the sphere for not just established players, but also a host of new entrants. As life sciences companies seek to develop cutting-edge formulas, they're also actively ramping up their product pipelines and going public to meet requisite capital requirements.

This rapid movement was observed in the 2017–2018 SEC filings as well, with many young companies submitting their S-1 prospectuses. This led to increased SEC scrutiny in a range of areas with substantial focus centered upon registrants further clarifying their R&D clinical trials, projected product pipelines, and current products and markets as well as making adequate disclosures throughout their statements.

Mergers and Acquisitions

In addition, while the life sciences mergers and acquisitions landscape remained rather dry in 2017, industry participants largely webbed out their research pipelines through licensing and collaborative agreements. A considerable portion of SEC examination also focused on applicants shedding greater light on the terms of their licensing and collaborative arrangements, along with explaining their relevant accounting treatments for the same.

The core objective behind these comments is to bring greater information transparency to investors, which inhibits potential discrepancies to keep market stability and confidence intact.

This report puts together a thorough examination, analysis, and comparison of the various SEC comments issued in 2017–2018, identifying possible patterns and changes in relation to the last study of 2015–2016. We believe such an assessment could assist middle market players in the life sciences industry, both pre- and post-IPO, to make improvements in the design and structure of their S-1, 10-K, 10-Q, and 20-F filings. This in turn reduces SEC approval delays resulting from lack of robust disclosure and noncompliance.

METHODOLOGY

To perform our analysis, we categorized all SEC comments directed toward companies in select life sciences subindustries during the review period. The following subindustries—identified by their EDGAR Standard Industrial Classification code—were covered in our analysis.

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 the focus of our study was middle-market companies, we excluded comments related to companies with market capitalization greater than $2 billion on the date of analysis from our research and assessment. Our analysis included comments filed on the SEC EDGAR database during the period from May 1, 2017, to April 30, 2018, which we'll refer to as 2017–2018.

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 an 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 2017–2018 and 2015–2016, respectively, were 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 given subset of comments from 2015–2016 to 2017–2018 exceeded the mean variance in that subset to be significant variances over the last 2 years. For example, out of the 610 comments directed toward S-1 filings in 2015–2016, 71 were related to R&D, amounting to a ratio of approximately 11.6%.

The same ratio increased to roughly 17.1% in 2017–2018, an increase of approximately 5.5%. 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, and places, as well as dollar figures, were omitted in the SEC sample comment sections.

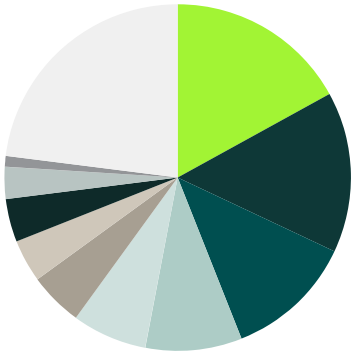
Trends in S-1 Filings

In the life-sciences industry, S-1 filings continue to get most of the attention when it comes to SEC scrutiny, encapsulating over 1,221 comments in this year's report.

This equates to a share of over 87% of total comments analyzed under S-1, 10-K, 10-Q, and 20-F filings. This trend remained somewhat consistent in 2015–2016, with pre-IPO companies making up 83% of the mix.

FIGURE 2: SEC Comment Categories for S-1 Filings

S-1 Filings, 2017–2018

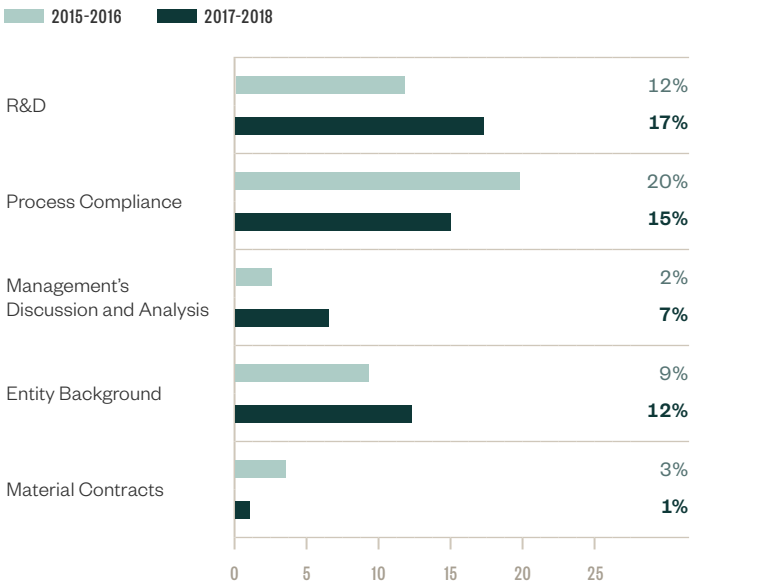


209	R&D*
184	Process Compliance
148	Entity Background
104	Initial Public Offering
80	Management's Discussion and Analysis
66	Disclosures About Risk
47	Shareholders' Equity
44	Licenses
40	Patents
13	Material Contracts
5	Disclosures About Directors
281	Other Less Significantly Recurring Comments
1,221	TOTAL COMMENTS

*R&D comments relate to clinical trials and studies, expenses, FDA filings and communications, product pipeline, products and services, and any other highly firm-specific comments.

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

S-1 Filings, 2015–2016 & 2017–2018 (%)

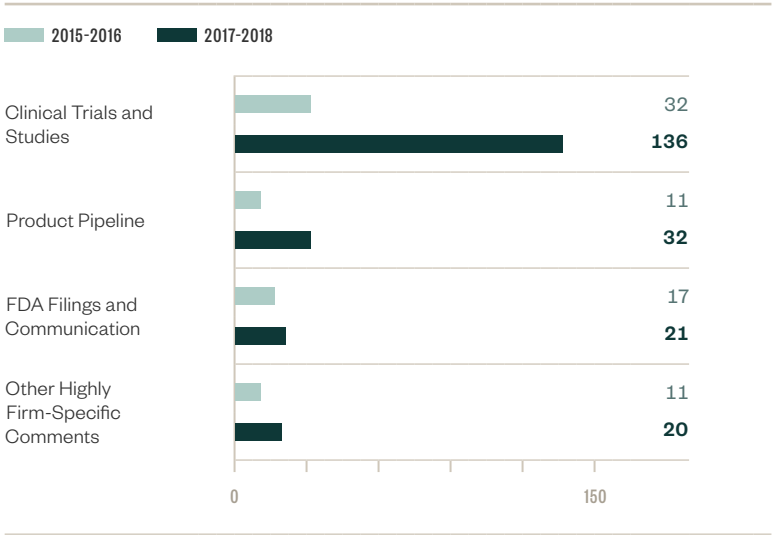


In the comparative analysis, we noted significant shifts in some specific categories of the life sciences industry. Comments directed toward R&D, management's discussion and analysis, and entity background proportionately increased by 3%–5% from 2015–2016.

Meanwhile, those under process compliance and material contracts experienced a moderate reduction by 5% and 2%, respectively. These areas are examined in greater detail in the coming sections.

R&D

FIGURE 4: Number of Comments | *By R&D-Related Subcategory*
S-1 Filings, 2015–2016 & 2017–2018



R&D is undeniably the lifeblood of the life sciences industry, driving the pace and breadth of product innovation. It's also one of the most sensitive and capital-intensive functions, yielding a substantial amount of SEC scrutiny every year, especially for new S-1 registrants.

This stems from Item 101 of Regulation S-K, which requires companies to make a thorough disclosure of their:

- General business activity, including historical research expenses undertaken for commercial activity
- Material product R&D to be carried out
- Any current and anticipated changes in R&D departments

It's unsurprising that R&D-related comments increased by roughly 5.5% from the previous report, representing a share of more than 17% of total S-1 comments in the 2017–2018 report. Information around companies' clinical trials, rolling product pipelines, and subsequent filings and communications with the FDA were of the greatest importance. These constituted roughly 65%, 15%, and 10% of the total number of comments, respectively.

The SEC consistently encourages applicants to clearly identify and describe their research activities, utilizing the data gathered from trials and studies to back up all product claims. Registrants must take extra care to make adequate and clear R&D disclosures throughout their prospectus, covering all relevant trials undertaken and any subsequent implications.

CLINICAL TRIALS AND STUDIES

Generically, clinical trials and studies attracted the greatest SEC scrutiny in the 2017–2018 report for S-1 filings, equating to a total of 136 comments. Its share of the total mix increased by over 20% from 2015–2016, with companies being requested to disclose trial dates, location, number of participants, dosage methodology, primary and secondary endpoints, and final results. This also

includes describing any serious adverse effects observed in the patients, along with subsequent steps taken to rectify the effects.

Meanwhile, the US Drug Enforcement Administration's decision to increase the amount of legally grown cannabis for research purposes is steadily fueling more comments around this topic, with a couple of such samples witnessed in 2017–2018.

The reason for such thorough SEC examination is to make sure companies provide sound details on their R&D approach, including a balanced disclosure that can provide insights on their product performance in the real market. This will inherently shed light on their future viability.

Sample Comments

> *For each of the clinical trials discussed in this section, to the extent that you have not already done so, please disclose the dates that such trials were conducted, where they were conducted, the number of participants, the method by which your products were administered, all serious adverse effects observed, primary and secondary endpoints, and the results of any completed trials.*

> *We note your statement in this section and throughout the filing that your wholly-owned subsidiary, [company name], "has begun a planned five-year Cannabis Genomic Study to complete a global genomic classification of the Cannabis plant genus" with the goal of use for medicinal purposes. Please further describe the current status of this work and how the company plans to move this study forward so that investors may better understand your business plan.*

> *We note your disclosure in the third paragraph on page 2 concerning the higher incidence of wet AMD. With reference to your disclosure on page 16, please revise the Summary to quantify the rate of incidence.*

DEVELOPMENTAL PRODUCT PIPELINES

An understanding of trials and studies should ultimately lead to a proper disclosure of the anticipated product pipeline, providing investors a clear time horizon on how each product candidate will be launched. Consequently, this area attracted a total of 32 comments in the 2017–2018 report, maintaining its significance as in 2015–2016.

Most of the comments were concerned with applicants' development pipeline charts, requesting them to remove programs that were too premature to be added in the list. The premise is to prevent misleading representations of the actual time needed to reach necessary milestones.

Sample Comments

> *Please revise your development pipeline chart on page 4 to remove the program that is in the discovery phase. Because you have not identified a product candidate for these programs, it is premature to highlight this program in your development table.*

> *The pipeline chart on page 4 seems to suggest that the various milestones represented in the table will be met and that each candidate will complete the phases of development portrayed in the chart, even though they are dependent on the achievement of successful trial results within the anticipated time frames. Please revise the chart to avoid giving the impression that these milestones will definitively be achieved within the time frames presented.*

> *We note your revised disclosure here. Please revise to indicate the status of development and regulatory status for each of the products you list in your product pipeline.*

FDA FILINGS AND COMMUNICATION

Clarifications around FDA filings made up the third-largest category within R&D for S-1 filings, given the importance placed upon proper adherence to FDA standards.

A total of 21 comments were made in the 2017–2018 report, seeking details on the submission and status of investigational new drug (IND) applications, which included the sponsor, subject matter, status etc. The SEC also requested companies to make additional disclosures around partial and full clinical holds placed by the FDA, including any response letters issued, and any subsequent actions taken by a company to make its study successful.

In light of this, companies should ideally present a detailed disclosure of all exchanges they have with the FDA in the course of obtaining relevant approvals.

Sample Comments

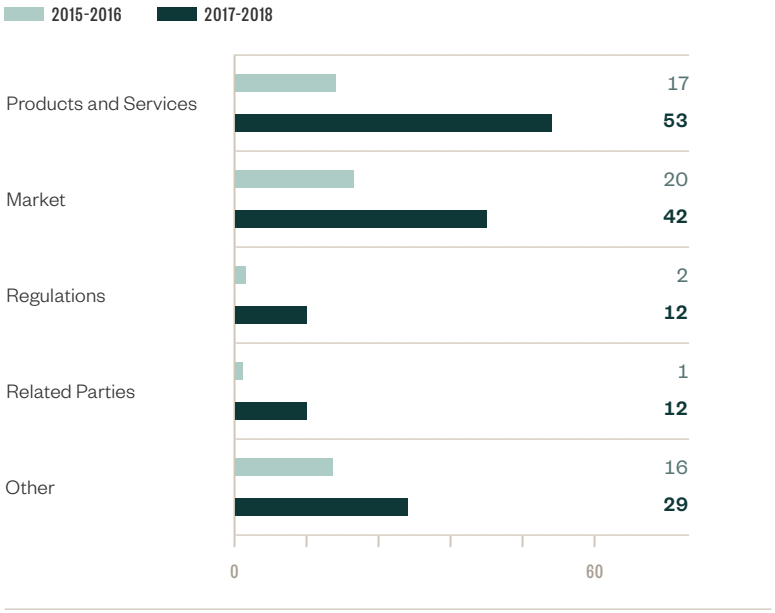
> *Please disclose here and in the Business section the details of your active IND for [product name], such as the date of filing, the sponsor, the subject matter and the status. Please include similar disclosure with respect to the EMA or any other drug regulatory authorities.*

> *We note your disclosure on page 20 that the FDA imposed a partial clinical hold on the cryopreserved part of the protocol covered by the IND application for [product name] until [company name] demonstrated comparability between the fresh and cryopreserved product. Please provide additional information regarding the comparability study that caused the FDA to remove the partial clinical hold, such as the results [company name] needed to achieve in order for the FDA to determine that the comparability study was successful. Please also revise the Business section to disclose when [product name] was placed on a partial clinical hold by the FDA and when the partial clinical hold was lifted.*

> *At first use, please revise your disclosure to provide a brief description of the FDA's Accelerated Approval Program.*

ENTITY-RELATED INFORMATION

FIGURE 5: Number of Comments | *By Entity-Related Subcategory*
S-1 Filings, 2015–2016 & 2017–2018



Comprehensive knowledge on a company's background is vital for investors. This is reflected by the prominence of SEC comments on entity-related matters, which requires registrants to detail their internal and external environments, covering areas such as legal structure, collaborative arrangements, products and services, target market, and applicable regulations. These disclosures can be made throughout the prospectus—in overall summary, business description, and risk factors—outlining the context behind any transactions and parties covered in the offering.

Entity-related disclosures increased by 3% from the previous report, constituting over 12% of total S-1 comments in the 2017–2018 report. While clarifications sought on overall products, services, and target markets continued to top the charts, supply-side agreements and related parties also received greater focus.

PRODUCTS AND SERVICES

Comments requiring disclosure on products and services accounted for over 35% of entity-related information, growing from 30.4% in 2015–2016. A majority of clarifications were directed toward registrants making a balanced disclosure on the advantages and risks associated with their product mix, along with any regulatory approvals sought for commercialization. They were also asked to refrain from making superfluous statements that could not be backed by objective data.

The SEC further required registrants to make disclosures as required by Item 101(h) of Regulation S-K, which requires smaller reporting companies to describe their general business procedures. This includes details such as principal products and markets, procurement of raw materials, distribution channels, and reliance on specific sets of customers.

Sample Comments

> *We note from your disclosure that some of your products appear to be genus or species specific. Disclose if pathogen identification and resistance profiling could be required before your product candidates, if approved, would be used and if the costs and timing associated with such tests, if any, would be a competitive disadvantage for your products as compared to the use of existing broad-spectrum antibiotics. Include risk factor disclosure as appropriate.*

> *Clearly explain each step you must take to commercialize your technology, including the material hurdles you must overcome at relevant junctures. If such information is 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.*

> *We refer to your statement on page 34 that your products are all made by independent vendors. Please disclose the names of your principal suppliers and the sources and availability of your raw materials. See Item 101(h)(4)(v) of Regulation S-K.*

EXTERNAL ENVIRONMENT

Giving an accurate and objective market-positioning statement, in view of current demand and competition dynamics, remains paramount. Comments related to the external environment remained the second-largest category, making up over 28% of the mix.

The SEC continued to challenge applicants' market-related claims, requiring them to provide supporting quantitative data on their target segments. This was especially relevant toward specific pharmaceutical preparations designed to address a niche patient population. Registrants were also asked if they commissioned any of the data they attributed to third parties, including the degree of involvement.

Sample Comments

> *Please provide the basis for your disclosure that one in three patients on [product name] and [product name] is expected to develop tNEPC and be eligible for treatment with [product name] and your estimate that approximately 20,000 patients with pancreatic cancer will be eligible for treatment with [product name] annually.*

> *We note the market data disclosed in your submission. Please revise to clarify how such data relates to the actual market that may be addressed by each of your products for the regulatory indications you intend to pursue.*

> *We note your reference to a physician survey conducted by [company name] on pages 4 and 70 as well as your statement on page 46 that you obtained industry, statistical and market data in this prospectus in part from surveys conducted by third parties. Please tell us whether you funded any of this research or commissioned any such reports. If so, please disclose your involvement and file the consent of the third party that prepared the information as an exhibit to the registration statement.*

REGULATIONS

Focus on regulatory issues grew to more than five times the amount in the previous report, constituting over 8% of the total S-1 entity-related comments. A variety of applicants, especially those involved in pharmaceutical preparations, were asked to further touch upon the regulatory scope for their drug candidates. They were also requested to outline their own operational plans and compliance mechanisms when operating in multiple jurisdictions. Adherence to the law remains critical.

Sample Comments

> *We note that you provide a summary of the U.S., EU and Israeli regulatory processes for the approval of drugs. We also note that you have a license to market [product name] in the U.S., Israel, Ukraine and China. Please expand your disclosure to discuss the regulatory pathway in jurisdictions where you plan to market [product name].*

> *We refer to your statement that your operations are potentially subject to a "complex web" of regulations. Please expand your disclosure to explain the regulations that may apply to your operations because your products involve cannabidiol, including tax regulations. Refer to Item 101(h)(4)(ix) of Regulation S-K.*

RELATED PARTIES

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.

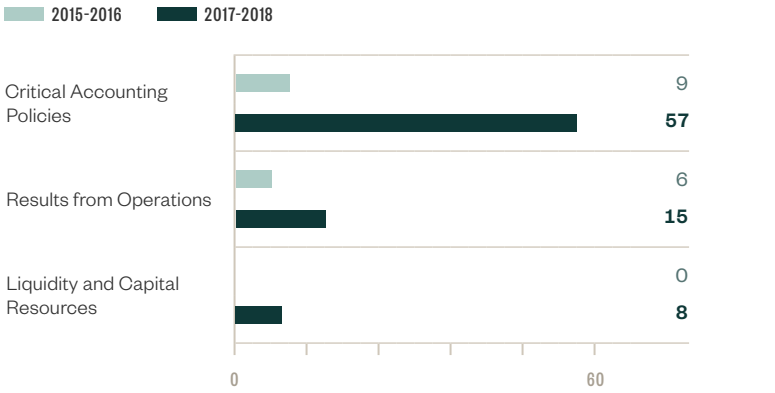
Sample Comments

> *Please revise your disclosure to clarify your statement that "related parties of the Placement Agent may derive material benefits as the result of these transactions." In this regard, it is unclear to which transactions you refer, how the related parties of the Placement Agent may benefit, the identity of these related parties and the Placement Agent's relationships with the related parties. Please also revise to clarify the basis on which the Placement Agent is a related party.*

> *We note that entities affiliated with [company name] beneficially own 58.4% of your shares, three of your five directors are affiliated with [company name] and [company name] provides scientific and technical, accounting, operations and back office support services to you. Please provide disclosure in the prospectus summary about your relationship with [company name].*

MANAGEMENT'S DISCUSSION AND ANALYSIS

FIGURE 6: Number of Comments | *By Management's Discussion and Analysis-Related Subcategory*
S-1 Filings, 2015–2016 & 2017–2018



Item 303 of Regulation S-K requires applicants to provide all parameters necessary for a clear understanding of their financial condition, which includes aspects such as liquidity, capital resources, operational results, off-balance sheet arrangements, contractual obligations, material changes, and safe harbor. The SEC's focus on this area increased by over 4% from 2015–2016, encapsulating a total of 80 comments for S-1 filings in the 2017–2018 report.

Keeping the growing importance of information symmetry and transparency in mind, it's always advisable for companies to zero in on all major operating activities that may require additional explanation, clarifying them in the prospectus. Meanwhile, all major assumptions should be duly stated and backed by objective references.

CRITICAL ACCOUNTING POLICIES

This was by far the largest topic for management's discussion and analysis in the 2017–2018 report at over 70% of the total, which equates to 57 comments. Most of the focus was on applicants disclosing changes in the fair value of their ordinary shares leading up to the IPO and estimated offering price to gauge how they account for equity issuances, cheap stock, and stock compensation.

Meanwhile, some of the comments also directed companies to provide additional detail on their accounting estimates, which included referencing relevant literature that supports their analysis.

Sample Comments

> *We may have additional comments on your accounting for equity issuances including stock based compensation and convertible instruments. Once you have an estimated offering price, please provide us an analysis explaining the reasons for the differences*

> *between the recent valuations of your common stock leading up to the IPO and the estimated offering price. Include the following in your analysis:*
>
> - *The issuance dates and the fair value of the underlying stock at each date; and*
> - *The significant factors, assumptions, methodologies used for each grant date.*

> *In addition, to the extent the common stock fair value significantly varies from the preferred stock issuance price, tell us the factors that contributed to the difference and explain how you considered the fact that the preferred stocks are convertible at a 1-for-1 ratio and are not redeemable.*

> *Tell us your accounting policy for and the nature of any sales returns, discounts and allowances and specify any differences in polices between direct sales and sales to distributors. Refer to SAB Topic 13A as appropriate.*

> *Please provide us with a full description of your accounting, including citation to authoritative accounting literature, for your license agreement with [company name] that became effective on June 23, 2015. As part of your write-up, include information about how you accounted for all fees incurred as of your most recent balance sheet date and how you plan to account for the annual anniversary fees going forward. Revise your disclosure of the license agreement terms on page 18 to quantify the amounts paid and consideration exchanged to date.*

RESULTS FROM OPERATIONS

While comments around operational results went down from their roughly 40% share in the previous report to 18.8% in the 2017–2018 report, they still represented the second-largest category.

In terms of content, the majority of the registrants were asked to explain changes in revenue in relation to sales and cost of sales, identifying the amounts attributable to changes in price and volume. Receipts and payments recognized for major supply and distribution arrangements were also questioned.

Applicants were also asked to reconcile statements made on their growth and company performance across the entire prospectus. For example, providing a historical growth percentage that isn't reflective of the current trend must be elaborated upon. Companies must make sure their statements correlate with the picture presented by their financial results.

Sample Comments

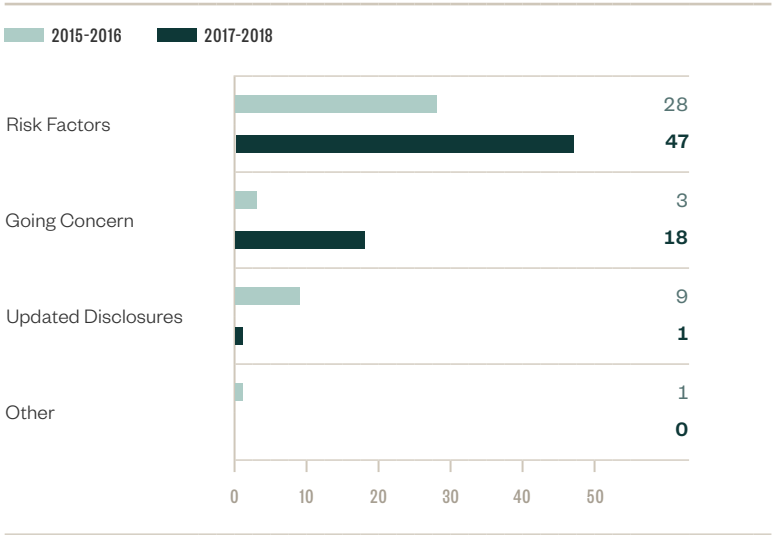
> *Revise your revenue disclosure to quantify the changes in your revenue during the periods presented that are attributable to changes in prices and changes in volume. Include quantification of the comparable amount of instruments sold in each period presented. Refer to Item 303(a)(3)(iii) of Regulation S-K.*

> *We note the disclosure regarding your 30% compound annual growth rate since 2011. If that percentage is not indicative of your growth during the most recent fiscal years or periods, as indicated by your disclosure on page 57, please revise to clarify and explain the reason for the lower growth. Also, if recent, lower growth is indicative of a material known trend, please provide the disclosure required by Item 303 of Regulation S-K.*

> *Please revise your disclosure to discuss your product sales and cost of sales in the periods presented, identifying any trends experienced to date. To the extent applicable, also disclose elsewhere in MD&A the general terms of any material manufacturing contracts with the independent vendors discussed on page 34. Separately disclose any minimum purchase obligations or other commitments under these contracts.*

RISK DISCLOSURES

FIGURE 7: Number of Comments | *By Risk-Related Subcategory*
S-1 Filings, 2015–2016 & 2017–2018



Life sciences is a capital-intensive and volatile industry, where long gestation periods for drug and medical device development operate amidst a fast-paced innovative environment. New discoveries can outrun their older counterparts in a relatively short span of time, making it imperative for companies to adequately disclose all short-term and long-term risks in a detailed manner, allowing stakeholders to make informed judgments.

This is provisioned by Item 503c of Regulation S-K, which requires registrants to furnish a prospectus summary and a discussion of significant risk factors that may stem from the following:

- A lack of operating history and profitability in recent periods
- Current financial position
- Existing and proposed business
- Dearth of a common equity market

Such risks need to be precise and primarily based on the registrant's own offering as opposed to being generic risks that affect all offerings. Each risk factor should be logically organized in a sub-caption format that adequately describes its nature and existence.

The tradeoff lies in putting in a comprehensive yet focused amount of risk disclosure, making sure all possible threats are well-reported. These threats could emerge from:

- External business or market-related environments
- Internal environments like internal control over financial reporting
- Other control-related procedures

The latter could include conflicts of interest at the executive level, the existence of organizational forum provisions that can inhibit shareholders' ability to bring a claim in judicial forums, or the continued concentration of ownership by management.

Meanwhile, financing appears to be another prime issue when it comes to managing capital in the life sciences industry. Companies must explain any liquidity constraints that can hamper operations or cause substantial doubt regarding their ability to continue, which includes disclosures of any existing covenants that restrict access to debt capital. The goal is to provide an exhaustive list of significant risks around the business and how the company plans to mitigate them.

While the comparative share of risk disclosures in relation to aggregate S-1 comments has fallen by 1.3% from the previous report to roughly 5.4% in the 2017–2018 report, this area remains an integral part of new applications. The SEC continued to demand a comprehensive risk backdrop that covers any threats and weaknesses associated with products, market, intellectual property, capital structure, and management personnel. Providing an objective and transparent framework is key.

Sample Comments

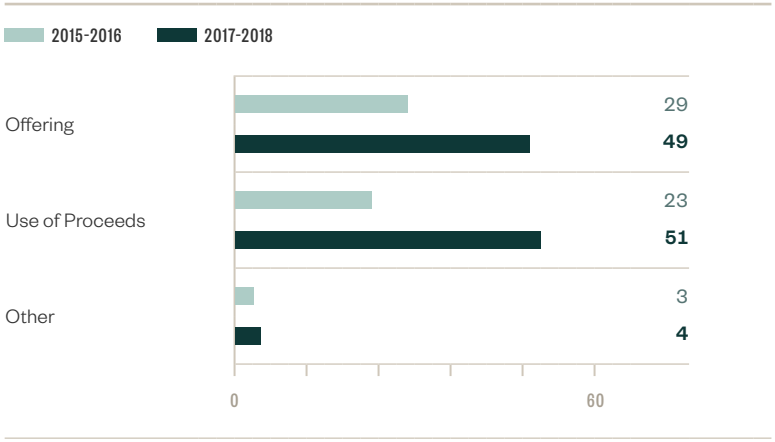
> *We refer to your last bullet of this risk factor. Please expand your discussion of the risks of your exclusive forum provision to include a discussion that such a provision may limit a shareholder's ability to bring a claim in a judicial forum that it finds favorable for such disputes and may discourage lawsuits with respect to such claims.*

> *Please add a risk factor to discuss potential conflicts that exist because the chairman of your board is also the co-founder and CEO of [company name], the counterparty to your license agreement for your lead product candidate.*

> *We note your disclosure that your Loan Agreement contains a negative pledge on intellectual property owned by you and if you raise additional funds through other arrangements such as collaborations, licensing or royalty-based financing arrangements, you may have to relinquish intellectual property rights or otherwise enter into arrangements on unfavorable terms. Please revise your disclosure to explain the specific circumstances that could result in the potential actions you discuss, including any material impact to the intellectual property relating to your [type of products] or your entry into third-party agreements relating to your [type of products].*

IPO-RELATED DISCLOSURES

FIGURE 8: Number of Comments | *By Initial Public Offering-Related Subcategory*
S-1 Filings, 2015–2016 & 2017–2018



Disclosures on the offering and use of proceeds are governed by Item 504 of Regulation S-K, which requires registrants to state the principal purposes of the issuance and the approximate amount required for each purpose. Meanwhile, registrants having no specific plan may want to have a general discussion of why they are going public.

While the overall share of disclosures in relation to total S-1 comments dipped 0.5% from the previous report, it continued to remain a significant topic for new filings with an 8.5% share in the 2017–2018 report.

OFFERING

Over 47% of the comments directed applicants to provide greater disclosure on their offering price, number of securities, and types of issuances, outlining their registration statement and cover page pursuant to Item 501 of Regulation S-K.

Many were also asked to reconcile minor discrepancies throughout the prospectus, which included information:

- Issuer name
- Underwriter
- Minimum and maximum shares to be placed
- Calculation of the registration fee

Sample Comments

> *Please tell us whether the recent market price set forth on the cover page of the prospectus will be used to determine the offering price. If you will not use the recent market price to set the offering price, then please include disclosure on the cover page indicating the factors that will be used to determine the offering price. For example, if the offering price will be determined through negotiations with the underwriters please include this information on the cover page.*

> *We note your disclosure on the prospectus cover page that the public offering price per share and warrant will be determined between you and the placement agent at the time of pricing yet you state in the plan of distribution that the public offering price was*

> *negotiated between you and the investors in consultation with the placement agent. Please revise to clarify how the public offering price will be determined.*

> *We note that this prospectus relates to both a primary offering and a secondary offering. Please revise your disclosure throughout the prospectus to clearly discuss the terms for each offering. For example, please revise the prospectus cover to clearly highlight at the top that there are two different offerings and the amounts of each offering, and revise your offering and summary offering sections to clearly discuss the terms of each offering. Please also revise the cover and elsewhere as applicable to discuss the duration of the secondary offering.*

USE OF PROCEEDS

The SEC is highly focused on how registrants plan to utilize funds raised in the offering, expecting them to clearly disclose all planned milestones. This expectation was reflected in the SEC's 2017–2018 S-1 related comments, of which almost 50% asked applicants to elaborate upon their use of proceeds. The majority of these comments required additional disclosure as per Instruction 3 of Item 504.

This highlights the importance of not only disclosing principal uses but also explaining if they require any material funding from sources other than the offering to meet their specified purposes, and stating the amounts sought. Such purposes could include the following:

- Completing all phases of clinical trials
- Seeking regulatory approvals
- Commercializing product candidates
- Maintaining working capital

Sample Comments

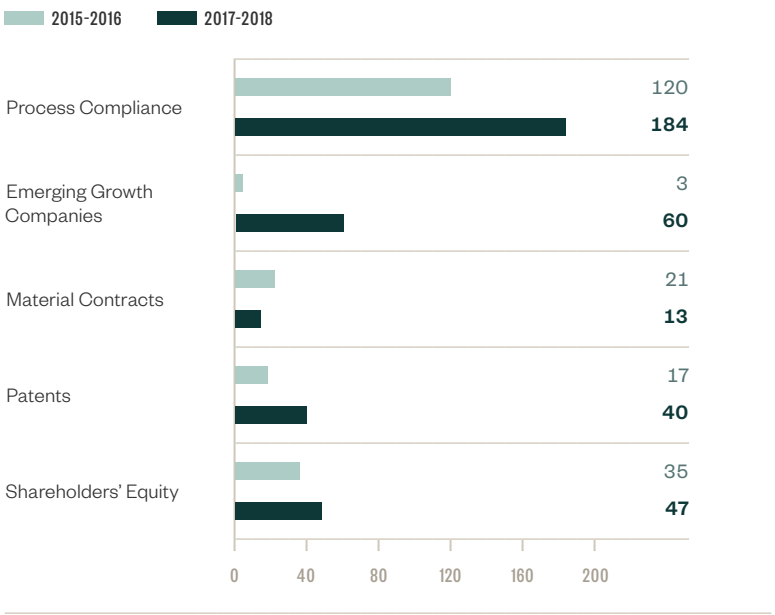
> *Please revise to disclose the approximate amounts intended to be used for each of the [product name] indications that you highlight in the pipeline chart presented on page 4 of the Summary. Disclose the sufficiency of the allocated funds to advance though the present stage and/or subsequent stages of development. If you will need additional funding to complete a particular stage of development, please disclose this point.*

> *We note your disclosure of the intended uses of proceeds in this section. If any material amounts of other funds are necessary to accomplish the specified purposes for which the proceeds are to be obtained, state the amounts and sources of such other funds needed for each such specified purpose and the sources thereof. Refer to Instruction 3 to Item 504 of Regulation S-K.*

> *It appears from your disclosure that the proceeds from the offering will not be sufficient to complete all of your specified uses. Please disclose how far in the development you expect to achieve with the proceeds of this offering and identify the sources of other funds needed to complete development of [product name] and [product name] through commercialization and establishment of your manufacturing facility. Refer to Instruction 3 to Item 504 of Regulation S-K.*

OTHER DISCLOSURE TOPICS

FIGURE 9: Number of Comments | *Related to Other Disclosure Topics*
S-1 Filings, 2015–2016 & 2017–2018



A wide range of other topics were covered in S-1 filings in the 2017–2018 report, including comments directed toward reporting, emerging-growth companies, material contracts, patents, and shareholders' equity. Out of these, reporting made up more than 53%.

REPORTING

Reporting remained a substantive focus, making up over 15% of S-1 comments in the 2017–2018 report. Many of these requested registrants to rectify their statements throughout the prospectus, which included removing reliance on regulations that aren't applicable to their offering or dismissing themselves from liability for information contained in the prospectus.

Meanwhile, procedural compliance is also pivotal. A significant number of comments requested companies to provide proofs on all graphics/visuals utilized in printed statements, carry out due filing of material agreements/exhibits, put forward note for confidential treatment as well as include all requisite signatories in the document.

Aspiring registrants should keep a lookout for all administrative matters when preparing their prospectuses.

Sample Comments

> *Please provide us proofs of any additional graphics, 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 you plan to enter into revised employment agreements upon effectiveness of the registration statement, as well as a stock option and incentive plan. Please file these as exhibits or tell us why you do not believe you are required to file them.*

> *We note your disclosure that the description of your capital stock is qualified in its entirety by reference to the applicable provisions of the DGCL. It is not appropriate to qualify your disclosure by reference to information that is not included in the prospectus or filed as an exhibit to the registration statement. Please revise accordingly.*

EMERGING-GROWTH COMPANIES

The onset of the Jumpstart Our Business Startups (JOBS) Act in 2012 catalyzed the growth of small businesses, helping them go public under the emerging-growth company (EGC) status. This created an influx with the majority of IPOs led by startups.

This trend was reflected in 2019 SEC comments. Unlike previous reports, over 60 comments were directed toward EGCs in S-1 filings, mainly requesting registrants for copies of all written communications as per Rule 405 of the Securities Act.

New registrants may want to familiarize themselves with all compliance matters under the Securities Act and elections made under the JOBS Act when filing for IPOs.

Sample Comments

> *Please provide us with supplemental 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.*

> *Indicate when you will make the election to pay the accrued but unpaid preference to the Series A Preferred Unit holders in cash or shares and how you will revise your disclosure to reflect such election.*

MATERIAL CONTRACTS

While the number of comments directed toward material contracts went down by roughly 2.4% from the previous report, they continue to remain an important category given the increased number of collaborations in this space. Companies are continuously partnering up across the value chain in order to double up on R&D, manufacturing and distribution expertise, while cutting down on costs.

Proper disclosure and description of such material contracts – especially contractual terms such as rights and obligations of parties, duration and termination of the agreement, and milestone payments –is paramount, as reflected by over 70% of SEC comments in this category this year.

Sample Comments

> *We note your disclosure on page 105 that [company name] may consent to an early release from the lock-up periods if in its opinion the market would not be adversely impacted by sales and in cases of a financial emergency of an officer, director or other stockholder. Please disclose whether [company name] needs the consent of any other party in order to obtain a release from the lock-up agreement.*

> *Please describe the material terms of your collaboration and license agreements, such as aggregate milestones and range of royalty payments. Alternatively, tell us why this disclosure is not material to investors.*

PATENTS

An indispensable component of the life sciences industry, patents act as a bedrock for recurrent investment in R&D and keeping innovation up and running.

Comments under this category—which fundamentally stem from Item 101(c)(iv) of Regulation S-K—saw a positive shift from 2.8% of total S-1 comments in 2015–2016 to 3.3% this year, with the majority directed toward pharmaceutical preparations. The SEC continues to actively inquire on the nature of patent-protection technology or product candidates, the type (composition of matter, process, or use), duration, and expiration as well as all applicable jurisdictions.

Such scrutiny will continue to prevail, given the importance of having sound intellectual property protection in the sector.

Sample Comments

> *You disclose that your patent strategy is multilayered, providing coverage of aspects of your core technology. We also note your disclosure regarding the first and second layers of your strategy. Please clarify if the capture antibodies are proprietary or sourced from third parties. Also clarify what you consider as your "core technology" and what you mean by the "fundamental methods for detecting single molecules independent of specific embodiments" and "specific embodiments of the core technology." Further explain the effect of your patents on these aspects of your technology.*

> *Please revise your disclosure to provide the following with respect to each of the granted patents you license:*
>
> - *the technology or product candidate to which it relates;*
> - *type of patent protection (composition of matter, process or use); and*
> - *the expiration date.*

> *Please expand your disclosure to specify the number of U.S. and foreign patents and the relevant foreign jurisdictions where you have issued patents or pending patent applications. Refer to Item 101(c)(iv) of Regulation S-K.*

SHAREHOLDERS' EQUITY

Providing a clear picture of capital structure includes details on the nature of shareholders' equity. This includes undertaking a thorough disclosure of the valuation of common and preferred stock, outlining majority ownership, showcasing key performance metrics such as earnings per share, and any changes in capitalization or potential dilution that can alter control.

While the share of equity-related comments in relation to total S-1 comments dipped by 1.9% from the previous report, this category remains important. In particular, the SEC made substantial inquiries on the following:

- Selling shareholders
- Each holder's name, nature of position, and material relationship with the applicant in the past three years
- Changes in the number of securities held before and after the offering under Item 507 of Regulation S-K

Sample Comments

> *Please revise your disclosure to state the nature of any position, office, or other material relationship between you or an affiliate and any selling security holder within the past three years. As examples only, we note that your director and executive officer [director name] holds the voting power for shares held by [company name], your director [director name] has voting and investment power for the shares held by [company name], your*

director [director name] is the CEO for [company name], and your director [director name] has voting and investment power over the shares held by three of the trusts. Refer to Item 507 of Regulation S-K.

Please disclose the material terms of your outstanding preferred stock, including the conversion rate into common stock, voting rights of the preferred holder and whether your CEO as the preferred shareholder must approve any particular corporate transactions. Please also include similar disclosure in Note 2 (Stockholders' Equity) to your financial statements. We also note that your certificate of incorporation refers to Ordinary A shares and Deferred shares. Please revise your disclosure to discuss these classes. In addition, we note that you are an S Corporation, and such corporations are subject to certain limitations such as having only one class of stock, having fewer than 100 holders, and that holders must be U.S. citizens or residents. Please reconcile these restrictions with your current structure. Please also add disclosure concerning the potential limitations and/or material risks to your business based on these restrictions.

With respect to any selling stockholder that would hold 1% or more after the offering, please revise your table on page 24 to show the percentage of the common stock that would be owned by such selling stockholder. If the primary and secondary offerings are concurrent, please include information reflecting the closing of the secondary offering and the closing of both offerings. Refer to Item 507 of Regulation S-K.

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

The aggregate share of comments in Forms 10-K, 10-Q, and 20-F in relation to the total number of comments dropped from 17% in 2015–2016 to 13% this year.

Prominent topics included process compliance, management's discussion and analysis, and R&D. Unlike S-1 filings, there was a greater focus on areas such as financial statements and material contracts.

FIGURE 10: SEC Comment Categories for 10-K, 10-Q & 20-F Filings

10-K, 10-Q, and 20-F Filings, 2017–2018

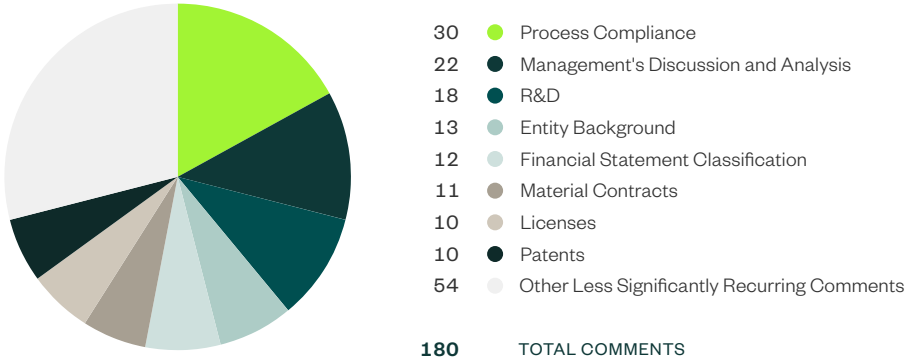
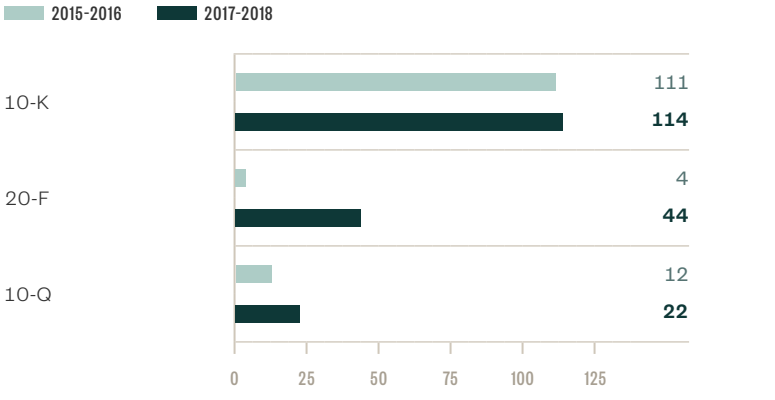


FIGURE 11: Breakdown of Comments | *By Filing Type*

10-K, 10-Q, and 20-F Filings, 2015–2016 & 2017–2018



Similar to previous findings, while the majority of the comments were directed toward 10-K filings, their share dropped from 87% in 2015–2016 to 63% this year.

As a result, the aggregate share of comments for 10-Q and 20-F filings went from 13% to more than 36%.

FIGURE 12: Key Areas of SEC Focus | *By Number of Comments*
10-K, 10-Q, and 20-F Filings, 2015–2016 & 2017–2018

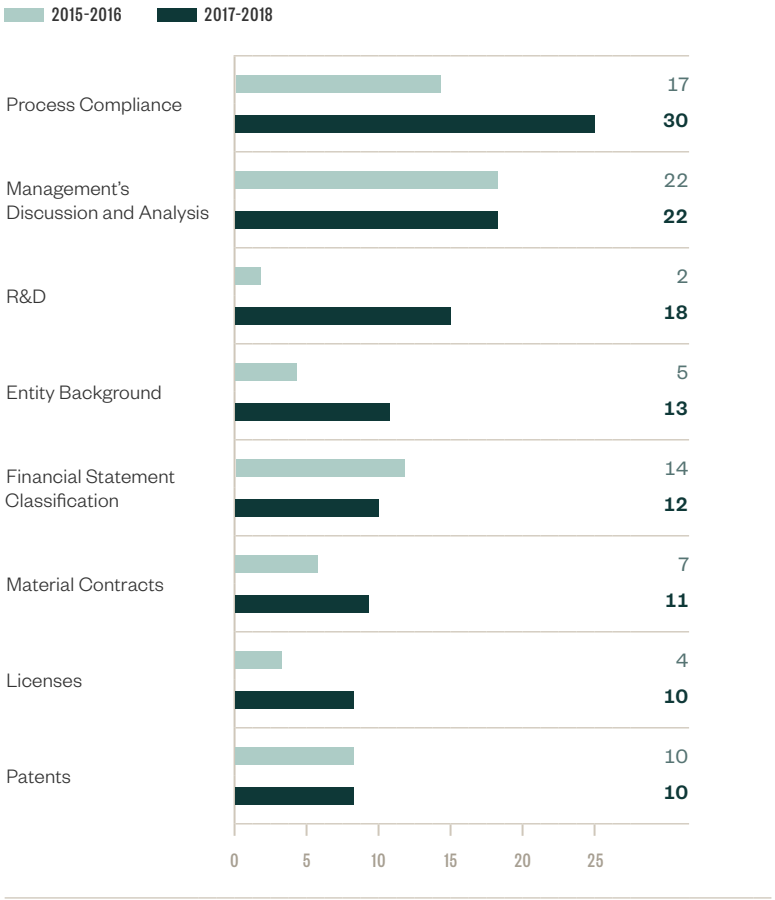
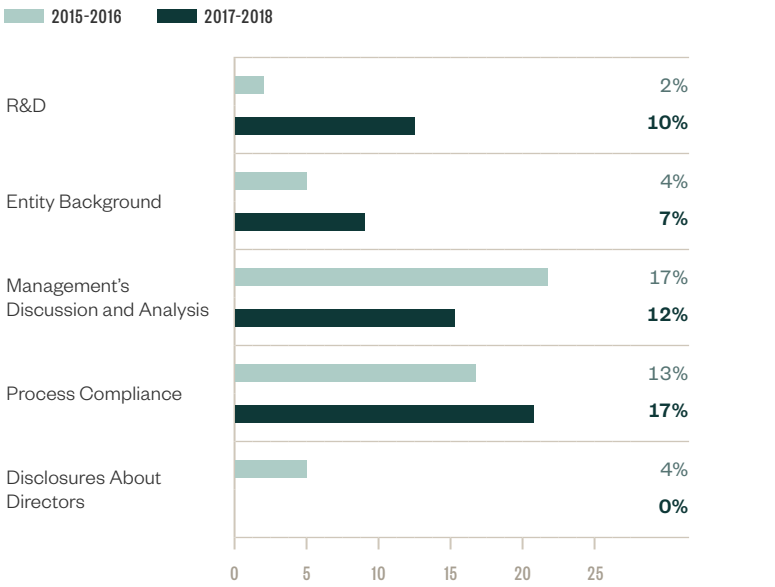


FIGURE 13: Significant Shifts in SEC Focus | *By Ratio of Comments*

10-K, 10-Q, and 20-F Filings, 2015–2016 & 2017–2018 (%)



Compared to the previous report, the SEC placed a significant focus on R&D this year, from 2% to 10%. In addition, categories such as reporting and entity background have steadily risen by 4% and 3%, respectively.

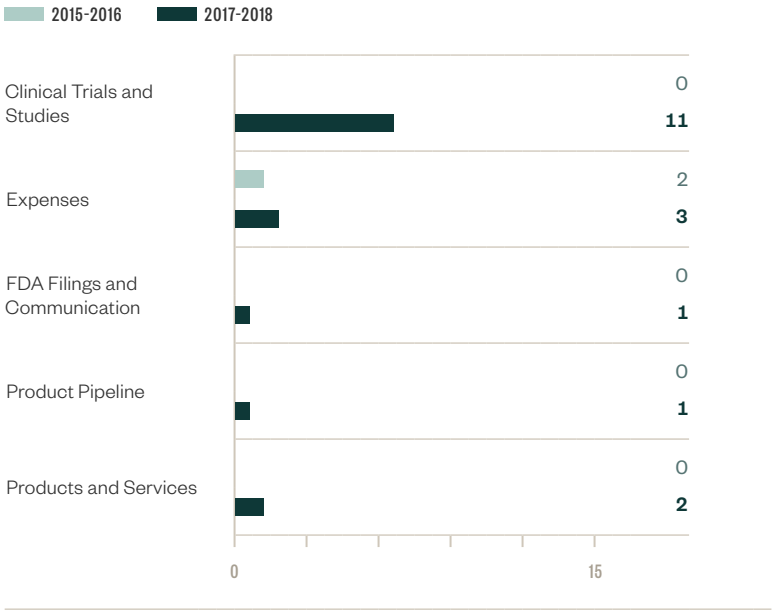
By comparison, management's discussion and analysis received less attention this year, with the ratio sliding from 17% to 12%. Unlike the previous year, there were no comments directed toward disclosures on directors, which could signify more efforts around compliance.

Nevertheless, these shifts shouldn't be construed as a reflection of what's important to be covered in filings. 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.

At the same time, this analysis is based upon a certain time period with a finite sample size. Companies should refrain from drawing any generic conclusions.

R&D

FIGURE 14: Number of Comments | *By R&D-Related Subcategory*
10-K, 10-Q, and 20-F Filings, 2015–2016 & 2017–2018



Comments related to R&D rose substantially in comparison to the previous report, increasing by almost 9%. Unlike 2015–2016, the SEC's focus was spread among a range of topics this year, with 61% of comments directed toward clinical trials and studies.

Similar to their S-1 filings, these companies were asked to disclose pertinent details regarding their product testing and studies, such as the scope and duration of each study, primary and secondary endpoints, and any serious adverse events. Some were also asked to comment on their collaborative research agreements, specifying the nature and contribution of every party in order to give a clearer picture of the activity net ahead.

Comments around R&D expenses and products and services comprised of 17% and 11% of the mix, respectively. Companies were largely asked to provide details on development expenses incurred for every project and quantify any nonproject related costs stemming from facilities, depreciation, stock-based compensation, and support services.

In addition, the SEC requested companies to provide a balanced disclosure of their anticipated products, clearly explaining all their features, any associated risks stemming out from the trials, as well as their plans to obtain FDA approval and patent protection for the same.

Sample Comments

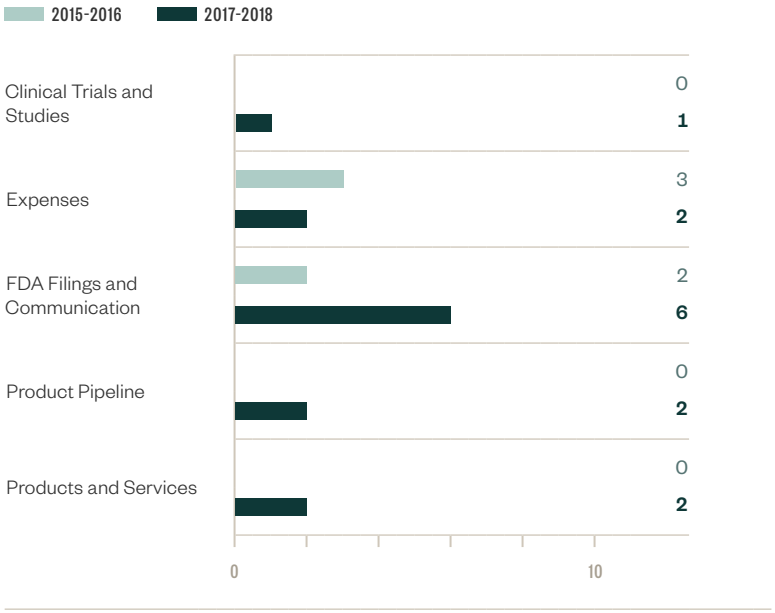
> *Tell us whether the studies have shown any material disadvantages or risks of your proposed products other than those mentioned in the fourth paragraph on page 5.*

We note your statement that your [therapy name] is currently in pre-clinical study and is undergoing animal testing. Please clarify your disclosure throughout the filing to disclose this status, and expand your disclosure here to provide specific details regarding the testing, such as the scope and design of the studies, primary and secondary endpoints, any serious adverse events, and the expected duration.

We note that research and development expenses directly charged to programs during 2016 make up only 50% of your total research and development expenses. Please tell us the research and development expenses incurred by types of costs, that were not directly charged to programs, such as facilities, depreciation, stock-based compensation and research and development support services for the year ended December 31, 2016 and for the quarters ended March 31, June 30 and September 30, 2017.

ENTITY-RELATED INFORMATION

FIGURE 15: Number of Comments | *By Entity-Related Subcategory*
10-K, 10-Q, and 20-F Filings, 2015–2016 & 2017–2018



Entity-related disclosures were another prominent topic for companies this year, rising 3.3% from the previous report. The products and services category constituted 46% of the mix, with the majority of comments requiring companies to expand upon their existing product and technology base. This involved factors like raw material procurement and product inspections, as well as validating any subjective claims.

Operations in restricted markets was another significant aspect this year. The SEC requested companies share their nature of contact in terms of direct sales, collaborative arrangements, contracts, and presence in environments subject to US economic sanctions and export controls.

It's advisable to place all disclosures in context, providing a holistic overview of the following:

- Internal frameworks such as products and services and in-house technology
- All relevant external implications such as supply-side arrangements and regulatory environments

Sample Comments

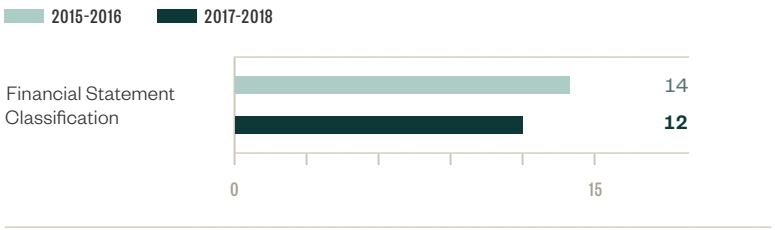
> *Please expand your disclosure in this section to address regulations that relate to the production of cannabis, as well as regulations regarding the reimbursement of health care expenses that may impact the pricing for your [therapy name]. Your discussion should address regulations in the United States and Canada that impact your operations, including the potential operations of [company name] if it receives the ACMPR license. We also note that you state in your third risk factor on page 14 that your products under development contain controlled substances. Please also clearly explain here and in the risk factor which DEA schedule of controlled substances (e.g., Schedule I) your products' components belong to, and the implications of such categorization.*

We refer to your statement in the first risk factor on page 24 that there are some material differences between the Ontario Business Corporations Act and laws generally applicable to U.S. corporations and shareholders. To the extent the OBCA is significantly different, please specifically explain the effect of such laws, including with respect to change in control transactions. Refer to Item 10.B. 9 of Form 20-F.

We refer to your statement that you generally only qualify a single source of API. In future filings, please expand your disclosure to discuss the availability of raw materials for your products. Refer to Item 101(c)(1)(iii) of Regulation S-K.

FINANCIAL STATEMENT CLASSIFICATION

FIGURE 16: Number of Comments | *By Financial Statement Classification-Related Subcategory*
10-K, 10-Q, and 20-F Filings, 2015–2016 & 2017–2018



While the number and share of comments directed toward financial statements declined by 14% from 2015–2016, the category continued to remain a significant topic.

Focus areas included the classification and presentation of various items, such as noncontrolling interests, deferred expenses, and losses incurred from operating and nonoperating activities. Companies were also asked to improve presentation, clarity, and legibility of their financial statements. This included:

- Consistently using parentheses to showcase any loss amounts
- Adopting a coherent approach towards presenting different types of expenses under applicable headings
- Reconciling line items

While there's no generic pattern to the type of information that may be required, the key takeaway for companies is to pay great attention to detail when it comes to preparing their financial statements. Any assumptions or judgments used should be objectively supported by relevant authoritative literature as in FASB's Accounting Standards Codification (ASC).

Sample Comments

> *We note that you begin this statement with net income excluding noncontrolling interests. Please revise future filings to provide amounts for both net income and comprehensive income attributable to the parent along with net income and comprehensive income attributable to the noncontrolling interest on the face of this statement. Refer to ASC 220-10-45-5 and 810-10-50-1A(a). This comment also applies to your statement of comprehensive income in your December 31, 2017 Form 10-Q.*

> *In future filings, to be consistent and to eliminate possible investor confusion, please use parentheses when presenting the operating loss, net loss, net loss per share and comprehensive loss amounts on this statement and elsewhere in the filing, similar to the manner in which they are presented on pages F-6 and F-7.*

> *You disclose that the 400,000 remaining [company name] options outstanding (without an employee put feature) have been recorded in equity as a noncontrolling interest. Provide us references to the authoritative literature on which you base classification of these options outstanding as a noncontrolling interest.*

OTHER DISCLOSURE TOPICS

REPORTING

Comments related to procedural compliance increased by more than 3% from the previous report at almost 17% this year. Common topics included:

- Requesting all relevant certifications with due references and the correct language
- Making relevant disclosures throughout filings
- Removing discrepancies between sections
- Filing all necessary exhibits and material

Providing a transparent and comprehensive picture is a must, which is why this area continues to remain of significant SEC interest every year.

Sample Comments

> *We note that your officer certifications provided in Exhibits 31.1 and 31.2 do not include the language referring to internal control over financial reporting that should appear in the introductory sentence of paragraph 4 and paragraph 4(b). Please amend your filings to include the correct certifications. You may file abbreviated amendments that include a cover page, explanatory note, signature page and paragraphs 1, 2, 4 and 5 of the certification. Refer to Exchange Act Rule 13a-14(a) and Item 601(b)(31) of Regulation S-K. This comment also applies to your Forms 10-Q for the quarterly periods ended March 31, 2017 and June 30, 2017.*

> *The independent audit report included in your filing references only the balance sheet as of March 31, 2017 and the related statements of operations, stockholders' equity and cash flows for the fiscal year then ended. Please amend your filing to include the independent auditor's report which relates to the remaining financial information included in the filing, i.e., the fiscal year ended March 31, 2016. Please refer to Article 3-01 and 3-02 of Regulation S-X.*

MATERIAL CONTRACTS

The SEC continued to focus on material contracts this year, with the majority of comments centered around key contract terms. This included having companies disclose the duration of important agreements, termination provisions, milestone payments and receipts, and the expiration of any relevant patents.

Sample Comments

> *In future filings, please expand your discussion of your material agreements to provide a description of the term and termination provisions of such agreements. If the term of the agreement coincides with the royalty term, which is connected to patent expiration, please also disclose any material patent expiration dates. If applicable, and if the royalty term is different from the term of the agreement, please also disclose the royalty term.*

> *In future filings, please expand your discussion of your material agreements to disclose for each agreement:*
>
> - *aggregate amounts paid or received to date;*
> - *aggregate potential milestone payments to be paid;*
> - *the percentages involved in any profit-sharing arrangements within a ten-point range;*
> - *the duration of the agreement; and*
> - *the termination provisions.*

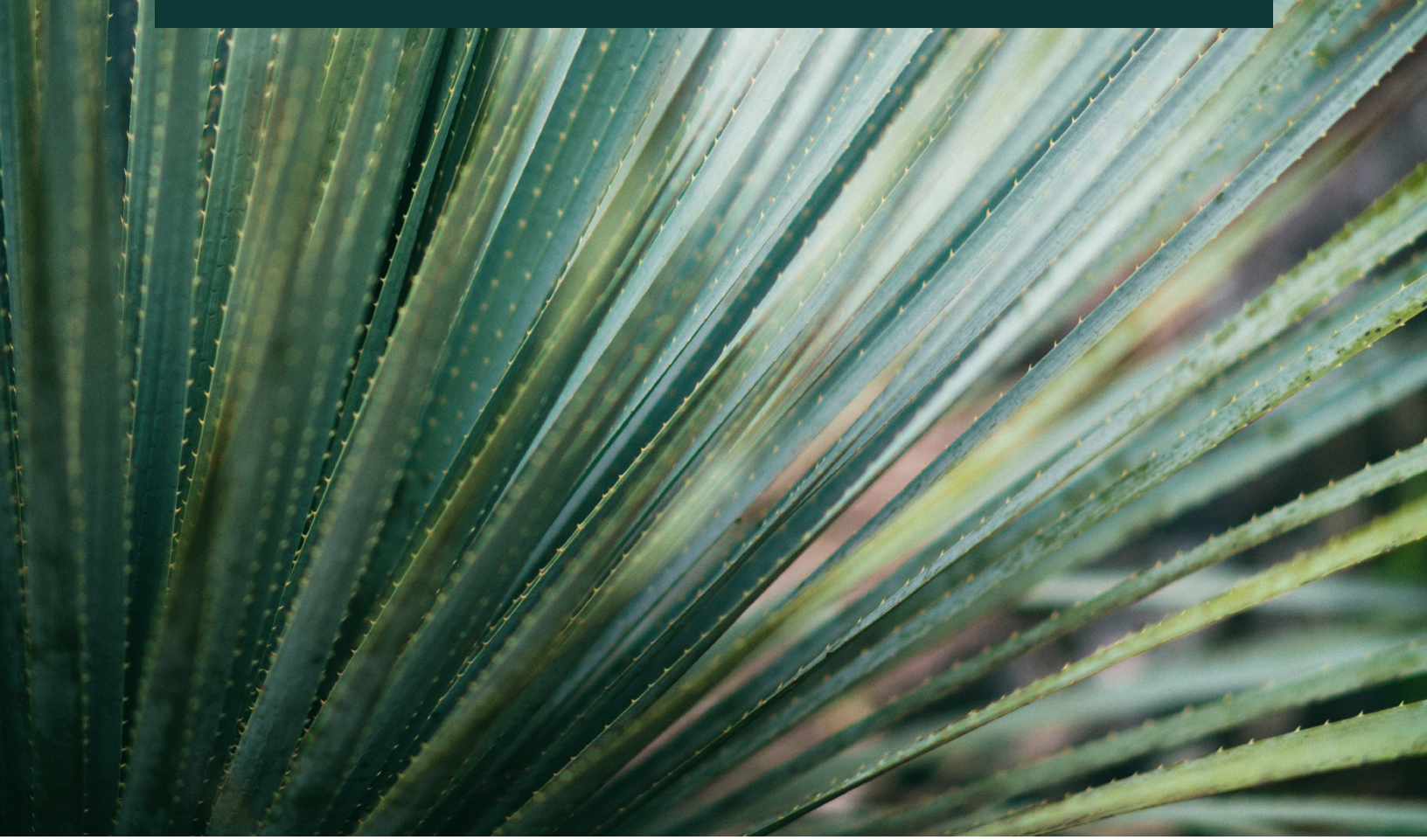
LICENSES

The focus on license agreements slightly increased from 2015–2016 with similar comments to material contracts. The majority were directed toward companies making adequate disclosures on their key terms and obligations, which included providing greater clarity on the amount of royalty to be paid—such as specifying a narrow royalty percentage range. In addition, many companies were also asked to include their license agreements as exhibits, pursuant to Item 601 of Regulation S-K.

Sample Comments

> *We note that you state on page F-39 that there is a royalty payable to [company name]. Please expand your disclosure in future filings to discuss the term and the royalty term of the [company name] license agreement assigned to you by [company name]. If the royalty term is connected to patent expiration, please also discuss the patent expiration dates. In addition, please file the license agreement as an exhibit. In the alternative, please provide us with an analysis as to why you believe this agreement is not a material contract pursuant to Item 601(b)(10) of Regulation S-K.*

> *We note your statement that [Company Name]'s licensing application is awaiting security approval. Please revise your disclosure to describe this approval process and explain the remaining steps in this process.*



MARKET CAPITALIZATION RANGES

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

Over 69% of the SEC's comments were centered on companies with a market capitalization of less than $500 million. Of the remaining, 19% were directed toward those between $500 million to $1 billion, while only 12% pertained to those greater than $1 billion but less than $2 billion. Smaller companies continue to attract the greatest scrutiny.

FIGURE 17: Trends in SEC Comment Categories | *By Market Capitalization Range*

10-K, 10-Q, and 20-F Filings, 2017–2018 (Number of Comments)

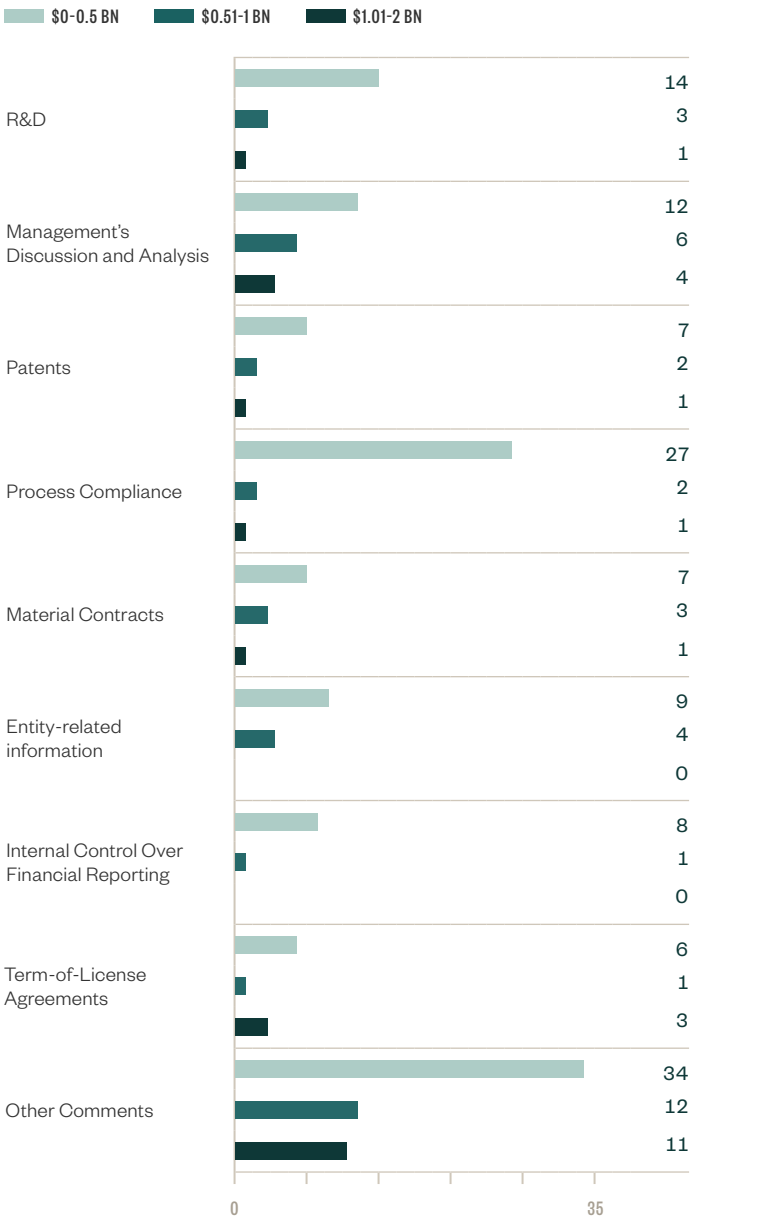
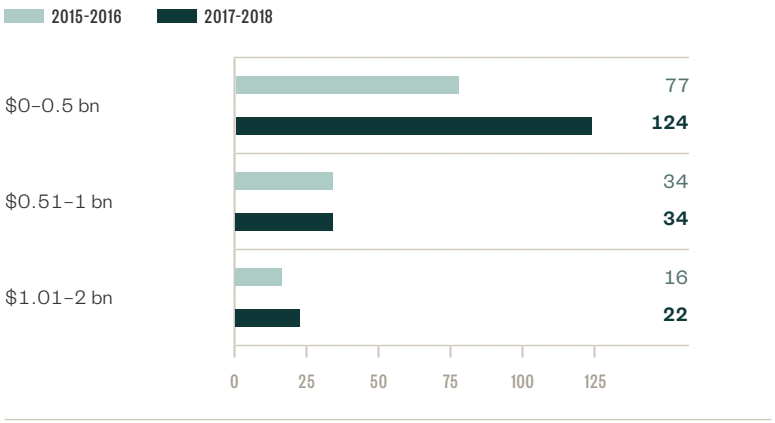


FIGURE 18: Breakdown of Comments | *By Market Capitalization Range*

10-K, 10-Q, and 20-F Filings, 2015–2016 & 2017–2018

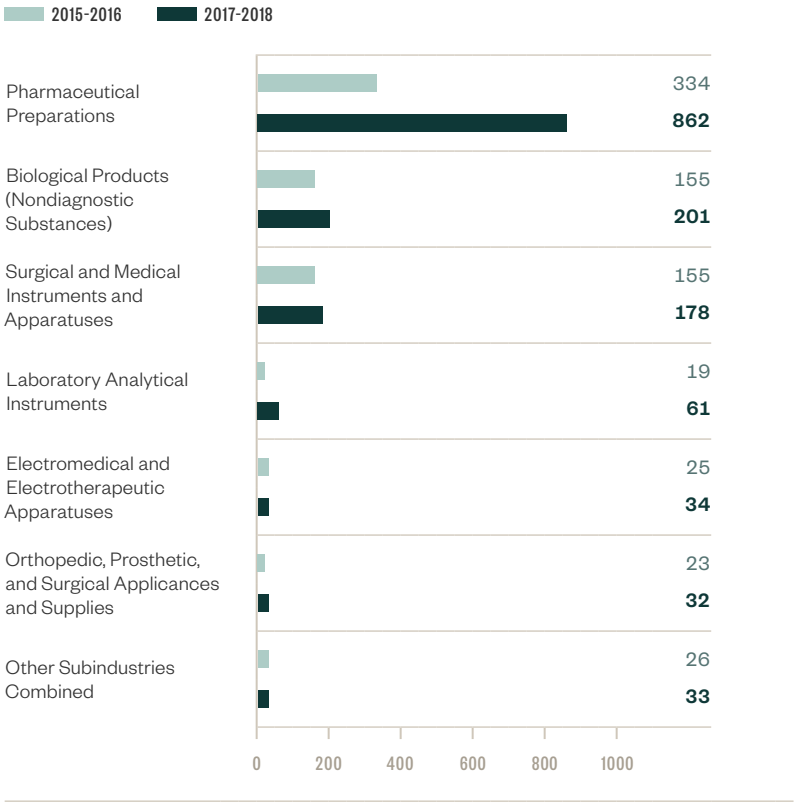


Company size and extent of SEC scrutiny theoretically have a negative correlation; in other words, the number of comments decreases as market capitalization increases. This corroborates the idea that smaller companies, having less market experience, may not be as well versed with SEC compliance and governance standards compared to their established counterparts. They seem to attract most of the SEC's attention in regards to making requisite disclosures, rectifying statements, and providing clarification.

The SEC seeks to ensure all necessary information is provided in the prospectus, presenting a true picture to investors.

SUBINDUSTRY TRENDS

FIGURE 19: Number of Comments | *By Subindustry*
10-K, 10-Q, and 20-F Filings, 2017–2018



The pharmaceutical preparations subindustry continued to be the main focus, with comments increasing from 45% in 2015–2016 to 62% in the 2017–2018 report.

The value chain is defined as manufacturing, fabricating, or processing drugs in pharmaceutical preparations for human or veterinary use. Unsurprisingly, R&D-related comments were the most common, making up 20% of the mix, which was followed by reporting at roughly 15%.

Much of the focus was placed on how well companies are carrying out their planned clinical trials and testing as well as how they work toward obtaining due regulatory approvals for mass production and marketing. Ultimately, the entire business model is driven by how well companies can cash in on their innovative formulas and exclusive commercialization rights, making disclosures highly critical.

In terms of other sectors, while the actual share of subindustries such as biological products and surgical and medical instruments and apparatus slightly decreased from the previous report, they continued to remain the next most significant areas, garnering a share of 14% and 13%, respectively. The breakdown of other sub-sectors in line was quite modest, swinging between 3–4%.

FIGURE 20: Major Variances in SEC Focus | *By Subindustry By Ratio of Comments*

10-K, 10-Q, and 20-F Filings, 2015–2016 & 2017–2018 (%)

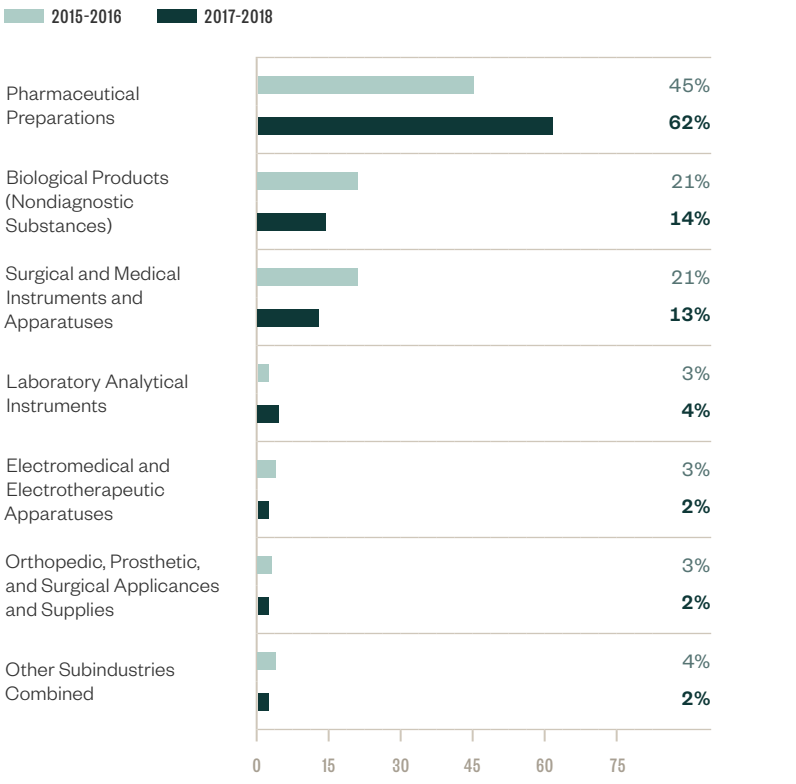
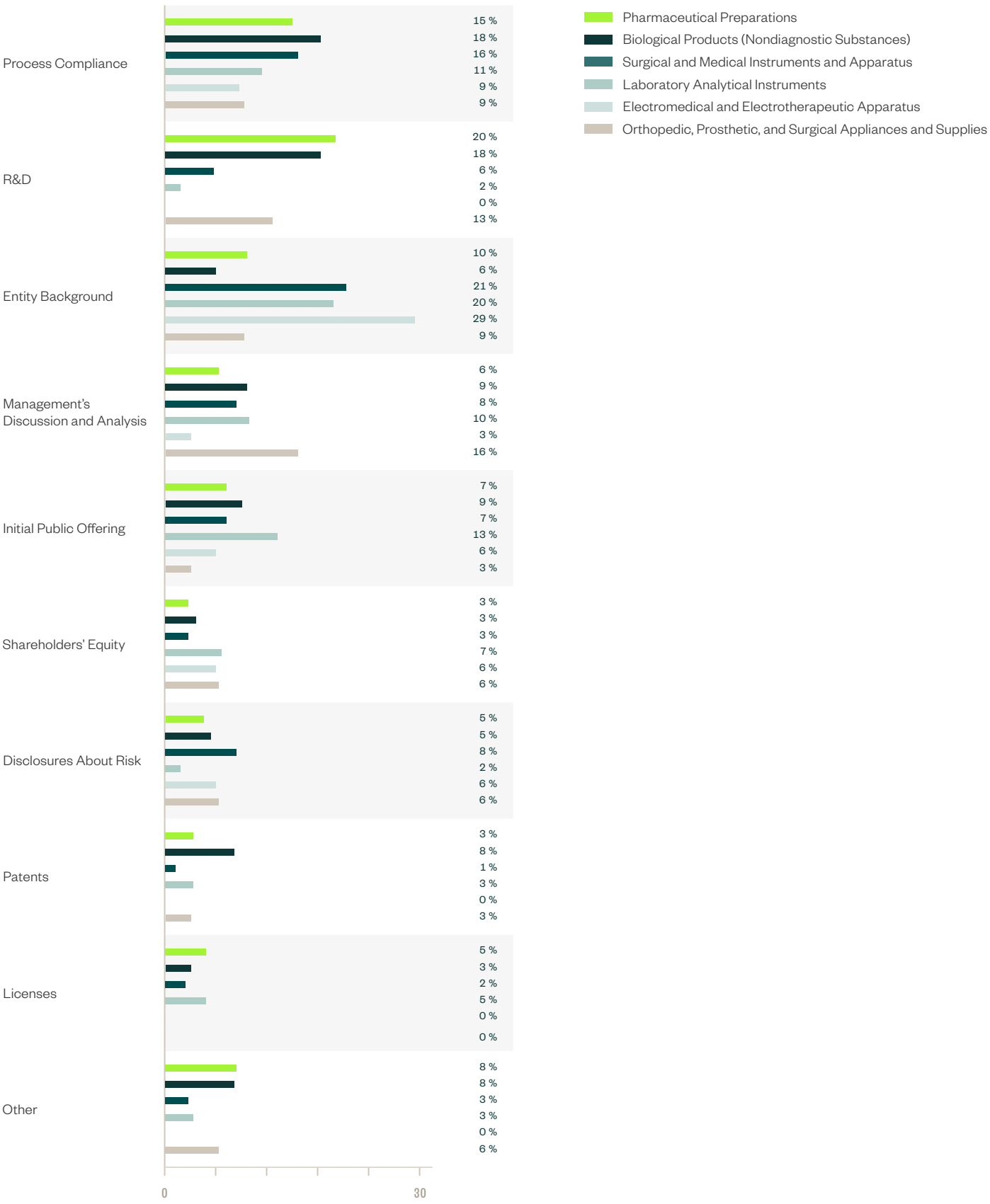


FIGURE 21: Share of Comment Categories | *By Ratio of Comments*

10-K, 10-Q, and 20-F Filings, 2017–2018 (%)



Given the inherent research-intensive nature of the entire life sciences sector, it's quite understandable that topics such as R&D and reporting continue to hold a pivotal role for the majority of the subindustries. Nevertheless, each subindustry is also quite distinct, based upon what it's delivering—drugs, apparatus, instruments, or other products. That means there can be varying degrees of scrutiny on each of the other SEC categories.

For example, disclosures around entity background were highly popular for many companies engaged in making instruments and apparatus in the 2017–2018 report. One such case was electromedical and electrotherapeutic apparatus, where entity-related comments constituted almost 30% of the subindustry's total comments. This was in stark comparison to the previous report, where 32% was related to reporting.

The key takeaway is that while some topics will continue to hold significant importance when it comes to the entire sector, other areas will differ by subindustry. Companies should pay close attention to their own value chains, identifying sensitive areas that may be of greater interest, and make sure to provide adequate disclosures and clarity.

At the same time, keeping tabs on market dynamics is also pertinent. The areas of scrutiny may be determined by external factors in the industry at a specific period of time.

Conclusion

The life sciences industry has always been at the forefront of innovation and technological advancement, where an experimental therapy can become obsolete in the blink of an eye.

Pressures continue to mount as companies grapple with rising costs, capital-intensive developmental pipelines, shorter product life-cycles, and ongoing patent expirations amidst an intense competitive landscape. At the same time, the entire sector is making a radical shift from a volume- to value-based care framework, focusing on quality long-term services. New entrants, ideas, and solutions change constantly.

COMPLIANCE STANDARDS

This means it's critical for companies to stay abreast of regulatory and compliance matters, increasing procedural efficiency to reduce delays. Adherence to SEC standards is a crucial component, because this governs conformance from the very first IPO registration statement to all subsequent filings required in the public domain.

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.

The SEC continued to seek clarity on a variety of topics in the 2017–2018 report, which can be analyzed from multiple perspectives. While new registrants were the focal point of review, post-IPO companies carried forward to maintain their fair share of comments.

POPULAR TOPICS

Popular topics included R&D and reporting. Companies were repeatedly asked to explain the characteristics and findings of all their clinical trials and studies. Concurrently, many were also asked to elaborate on their entity background, which included commenting on their existing product and technology portfolio, ongoing collaborations in the form of contractual relationships and licenses, and the essence behind current operating results.

The SEC also requested a number of companies make requisite disclosures and format their statements pursuant to Regulations S-K and S-X, highlighting the fact that legal and administrative obligations are imperative. It can be as simple as including the right signatures or filing the right documents.

Consequently, this report aims to familiarize companies with the comprehensive nature of information required in various parts of the statement. This applies to not only mid-cap companies included in the scope of this analysis but all other current and future registrants.

Gaining insights from these generic trends and having additional oversight from specialist advisors can help companies anticipate and avoid impending obstacles. In other words, preventing simple mistakes can help companies save time and money.

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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We serve organizations of all sizes—from large multinational companies and publicly traded middle-market corporations to private companies and start-ups. Our clients specialize in many areas, including:

- Biotechnology
- Diagnostics
- Medical devices
- Pharmaceuticals
- Digital health

Gain deep resources and industry expertise at every step of your business life cycle, whether you're facing an audit, needing to reduce risk, or preparing for an initial public offering. Moss Adams is also the only middle-market firm with five professionals who served two-year terms as fellows at the SEC.

About Moss Adams

With more than 3,200 professionals across 25-plus locations in the West and beyond, Moss Adams provides the world's most innovative companies with specialized accounting, consulting, and wealth management services to help them embrace emerging opportunity. Discover how Moss Adams is bringing more West to business.

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