

23 November 2021

Manager, Company Announcements  
ASX Limited  
Level 4  
20 Bridge Street  
SYDNEY NSW 2000

**Via E-Lodgement**

Dear Sir/Madam

**Mayne Pharma Group Limited**

Please find attached the presentation and addresses to shareholders to be delivered by the Chair and the Chief Executive Officer at Mayne Pharma's Annual General Meeting today at 9.00am (Melbourne time).

The meeting will be webcast at <https://web.lumiagm.com/#/m/397184492>.

For further information about the Annual General Meeting please refer to <https://www.maynepharmaceutical.com/investor-relations/annual-general-meeting/>.

This announcement is authorised by the Board.

Yours faithfully,  
Mayne Pharma Group Limited



Laura Loftus  
Company Secretary

**For further information, please contact**

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## 2021 ANNUAL GENERAL MEETING

AT 9.00 AM ON 23 NOVEMBER 2021

### CHAIR'S ADDRESS

Welcome everyone, I'm Frank Condella, the Chair of Mayne Pharma. It is a pleasure to welcome you to Mayne Pharma's 2021 Annual General Meeting. As we have a quorum present, I am delighted to open the meeting.

First of all, I would like to take you through the procedural aspects of the meeting today. Unfortunately, due to the COVID-19 pandemic, we cannot physically meet in person and are hosting the meeting virtually using the Lumi platform. By using this technology last year we saw our AGM attendance increase 80% on the prior year which we believe is a positive outcome.

If you experience any difficulties during the meeting please call the AGM help line on +61 3 9415 4024 which is listed in the AGM user guide on our website and appears on the screen. If there are any technology issues, a recording will be available on our website after the meeting.

Shareholders and proxy holders have the ability to ask questions and submit votes. You can ask questions during the meeting in two ways. You can ask a question in writing by selecting the messaging tab at the top of the Lumi webcast. For those who wish to ask an oral question, please pause the broadcast on the Lumi webcast and then click on the link for asking audio questions. A new page will open where you will be asked to enter your name and topic of your question before being connected. If you have any issues using this system, please return to the Lumi webcast.

Text questions can be submitted at any time through the online platform and you do not need to wait for the relevant item of business to ask your questions. We encourage you to lodge any text questions now.

We will address questions at the relevant time in the meeting and questions may be moderated or if we receive multiple questions on one topic they will be combined together. Finally, due to time constraints, it is possible that we may not be able to answer all questions. If that occurs, then we will revert back to you individually after the meeting about your unanswered question.

Voting today will be conducted by way of a poll on all items of business. Voting for all resolutions is now open and will remain open during the AGM. If you are eligible to vote at this meeting, a polling icon should be displayed on your screen. Click on this icon which will bring up a list of resolutions and present you with voting options. To cast your

vote, select one of the available options. You have the ability to change your vote up until the time I declare the voting is closed at which time your most recent selection will be registered.

I would now like to introduce our Board members, senior executives, and the Company's auditor who are all online today. Joining me in Raleigh, North Carolina is our CEO Scott Richards, and fellow directors Patrick Blake and Dr Carolyn Myers. I am very pleased to welcome Carolyn who was nominated by our largest shareholder Mithra Pharmaceuticals as prescribed under our license and supply agreement to commercialise NEXTSTELLIS® in the US. Carolyn is an experienced pharma executive with more than 30 years of industry experience in creating, growing and leading health care businesses.

In Australia, we have our Deputy Chair Ian Scholes and Directors Nancy Dolan and Professor Bruce Robinson, our CFO Peter Paltoglou and David Petersen, the Company's auditor. We also have online Lisa Pendlebury, VP of Investor Relations and our Company Secretary, Laura Loftus who will moderate the shareholder questions.

I'll now outline the procedure for today's meeting. There are three items of business on today's agenda:

1. I will present my Chair's Report, then
2. Scott will provide an update on the business, and then
3. We will go into the formal part of the meeting where we will vote on the resolutions outlined in the notice of meeting.

## **I will now move to the Chair's Report.**

As most of you know, FY21 has been another challenging year impacted by a number of external factors including the global pandemic, ongoing competitive pressure in the retail generic market and increasing demands from payors for insurance coverage across our brand portfolio. We have also seen the USD weaken which has impacted our results as they are reported in AUD.

Your Board and management team are very disappointed in the financial performance of the Group and are committed to turning around performance and seeking out the best opportunities to maximise shareholder value.

Mayne Pharma has a diverse and complex operating model of brands, generics and contract services which provides us with multiple opportunities for growth and potential value creation.

For instance, the recent FDA approval and launch of the novel contraceptive NEXTSTELLIS in the US is our most significant commercial opportunity. NEXTSTELLIS competes in the US\$3.4b short-acting combined hormonal contraceptive (CHC) market with nearly 10 million American women using CHCs for their contraceptive needs. NEXTSTELLIS is a new birth control option that contains estetrol or E4, the first new estrogen introduced in the US in more than 50 years. E4 is a low impact estrogen with a unique mechanism of action that offers potential advantages over other estrogens.

In terms of other near-term growth opportunities, we are focused on broadening our dermatology and women's health portfolios and evolving our go-to-market distribution model. In dermatology, we have doubled our product portfolio through a number of new supply and distribution agreements with leading pharma companies. These agreements demonstrate how our unique business model in dermatology, which focuses on providing better outcomes for patients, prescribers and pharmacy partners, is attracting new partnerships and new revenue opportunities

In women's health, we continue to advance the generic NUVARING® program. Whilst we unfortunately received another complete response letter (CRL) from the FDA, I can say the number of questions were minimal and we have submitted our response to the FDA. The NUVARING market opportunity remains significant with two independent generics approved and an addressable market of US\$660m<sup>1</sup>.

Our US contract service business, Metrics, continues to demonstrate a solid track record of financial performance delivering 12% revenue CAGR over the eight years we have owned the business. M&A dynamics remain strong in the CDMO market with many businesses being sold for trailing 12-month EBITDA multiples in the mid to high teens. With almost US\$30m of operating profit<sup>2</sup> in FY21, Metrics remains a highly valued asset. We continue to invest in expanding the capability and capacity of the Greenville site as well as improving our commercial and operational processes.

Our International business which operates out of Salisbury, South Australia also has a solid track record of growth delivering 5% revenue CAGR over the last six years. The Salisbury facility remains the largest Australian-owned full service oral solid dosage plant to manufacture TGA and FDA-registered pharmaceuticals.

Moving to the FY21 results.

The Company reported revenue of A\$401m, EBITDA of A\$66m and underlying EBITDA of A\$75m excluding NEXTSTELLIS set up costs. Disappointingly we reported a net loss after tax which was impacted by the non-cash intangible asset impairments of the generic portfolio. On a constant currency basis, revenue was down 3%, reported EBITDA down 5% and underlying EBITDA down 10% versus the prior corresponding period (pcp).

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<sup>1</sup> IQVIA MAT Sales, September 2021

<sup>2</sup> Operating profit is gross profit less direct operating expenses and excludes depreciation

Pleasingly, all segments other than Generic Products contributed to EBITDA growth compared to the pcp. Metrics Contract Services performed strongly with gross profit up 18% on pcp in USD terms benefiting from new commercial manufacturing revenues. Our International segment delivered 20% growth in gross profit benefiting from improved overhead recovery rates with growing production volumes. Specialty Products was flat at the gross profit line due to key dermatology brands and TOLSURA® being impacted by COVID-19, as well as a more challenging payor environment driving increased rebates for insurance coverage. The restructure of the dermatology sales team however, drove significant improvement in operating profitability after direct operating expenses. The final segment, Generic Products was significantly impacted by new competition on key products and pricing pressures across the portfolio.

In FY21, we achieved \$18m operating expense reduction on a constant currency basis excluding NEXTSTELLIS set up costs. We continue to optimise our cost base through the realignment of our supply chain with raw material suppliers and contract manufacturing organisations.

The Company generated net operating cashflow of \$59m in FY21, reduced net debt by \$11m to \$249m and was compliant with all bank covenants at balance date.

Before handing over to Scott, I wanted to take a moment and thank Roger Corbett and Bruce Mathieson for their valuable contributions during their many years of service on the Board of Mayne Pharma. We will continue to evolve our Board over the coming year and expect to add new directors with a variety of skills that will help to guide the company strategically. We hope to announce more on this early next year.

As I said earlier, Mayne Pharma has a diverse group of businesses that provide us with various opportunities for growth. I, along with our new and existing directors, will focus on developing the strategic direction for our company that we believe will most increase value for all of us shareholders.

On behalf of the entire Board I want to thank all my colleagues for their hard work and contribution through these challenging times and to all our shareholders for your continued support.

With that, I will now hand over to Scott.



## 2021 ANNUAL GENERAL MEETING

AT 9.00 AM ON 23 NOVEMBER 2021

### CEO'S ADDRESS

Thank you, Frank. Good morning, everyone.

Today I will provide you with an update on the launch of NEXTSTELLIS® our novel contraceptive which received FDA approval earlier this year together with some comments around our evolving specialty products business model and our outlook.

### NEXTSTELLIS update

I know most of you are very interested in how NEXTSTELLIS® is tracking. In late June we launched and shipped product to the wholesalers and our sales team commenced distribution of samples to health care providers or HCPs. The key priorities with the launch have been to educate the market about our new estrogen, E4, differentiate NEXTSTELLIS from other branded contraceptives, gain broad payer acceptance, and ensure patients have a seamless experience accessing the product.

As a reminder, NEXTSTELLIS is a combined oral contraceptive containing a natural, low impact estrogen with a unique mechanism of action. It's been 50 years since a new estrogen was approved for contraceptive use in the US and therefore a heavy medical and sales effort is required in the launch phase particularly around educating HCPs on the science of E4.

Our marketing strategy is currently focused on HCPs. To date, our sales team have had 50,000 interactions with HCPs and hosted 5,000 education lunches. Further, 23 key opinion leader speaker events are scheduled this quarter. Among our target HCP's, aided awareness of NEXTSTELLIS has grown from 2% at launch to 68% and of those HCPs that are aware of NEXTSTELLIS, 49% have an intent to prescribe<sup>1</sup>.

We have made strong progress with payer coverage since we reported our full year results in August. Commercially insured patients which make up ~85% of the market have 67% plan access of which 55% is unrestricted. Unrestricted access has increased from 38% in August and is on track to be on par with other branded contraceptives over the coming year. Payer coverage is a key component in creating affordable patient access to NEXTSTELLIS and eliminating a key concern that HCPs have during launch phase of a brand.

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<sup>1</sup> ATU market research survey of target HCPs, August 2021

In terms of how this activity translates into underlying demand, we are seeing growth in all key metrics including the number of writers and the numbers of scrips written and dispensed each week. Since launch, there have been over 850 new prescribers who have written more than 7,000 prescriptions of which more than 3,000 have been dispensed. The difference between written and dispensed prescriptions reflects ongoing use of samples by patients and abandoned prescriptions due to access issues. In the early launch phase of a brand the abandonment rate can be relatively high and over time this improves as patient's health plans adopt the product – and that's exactly what we are seeing.

Based on growing HCP awareness levels and their intent to prescribe, patient sampling dynamics, recent coverage wins and optimisation of our patient co-pay support program, we are confident there will be a significant step up in dispensed prescriptions in the coming months. Put another way, we know that prescribing materially steps up once HCPs have received 6 calls and have sampled 12 patients. As at the current day, we have only reached 14% of our target universe of 8,200 high decile prescribers at this 6-call threshold. A further 35% or approximately 3,000 prescribers will cross this 6-call threshold over the next 4 weeks.

The final piece of the jigsaw is turning on our direct-to-consumer (or DTC) campaign. We plan to do this in the new year once we have reached certain milestones around HCP awareness, unrestricted payer coverage and a targeted number of writers. This will be an exciting phase of growth for NEXTSTELLIS given we know that more than 50% of conversations with HCPs about contraceptives are initiated by consumers and greater than 80% of the time brand requests are granted.

In summary, while it is early days in our launch, we are very excited about the potential of NEXTSTELLIS to become a leading brand in the short-acting combined hormonal contraceptive (CHC) market which is valued at US\$3.4b with more than 60 million prescriptions written annually<sup>2</sup>.

### **Evolving US pharma market**

I now want to make a few comments about the US pharma market. Whilst the largest in the world and valued at US\$500b in ex-manufacturer sales terms<sup>2</sup>, it is incredibly complex and dynamic for all participants including patients, prescribers, retailers, wholesalers, PBMS, insurers and manufacturers like Mayne Pharma. In recent years, dramatic consolidation of generic drug buying groups, pharmacy benefit managers (PBMs) and health insurers has created significant downward pressure on manufacturers margins, both generic and specialty brands. At the same time the out of pocket cost of drugs to patients is rising and prescribers are being given less choice on patient treatment. In many therapeutic areas, PBMs are making coverage harder and adding restrictions or blocking products outright. In dermatology for instance

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<sup>2</sup> IQVIA, MAT Sales September 2021



## ASX Announcement

unrestricted commercial coverage has dropped from 44% in mid-2020 to 30% on our foam brands making it increasingly harder to capture value in the traditional way. This is an industry wide challenge, not company specific. A cost shift from downstream actors to manufacturers and patients is happening and will potentially gather pace.

These dynamics are creating opportunities to generate an improved value proposition for prescribers and patients. New businesses and alternate go-to-market models are being created to provide greater transparency, cost savings and convenience for patients. For example, GoodRx is one business that seeks to make healthcare more affordable by giving consumers access to medicines that they otherwise wouldn't have been able to afford. Amazon pharmacy is another disruptor who is providing consumers with prescriptions through their online store.

Mayne Pharma is focused on evolving its business model through leveraging new technologies, capitalising on disruption across the entire US pharma value chain, and removing inefficiencies for prescribers and patients alike. In dermatology, our largest therapeutic category, we are most advanced in this pursuit having established a portfolio-based selling model offered across multiple channels, with the objective of moving us closer to the patient to enable participation in the full value chain.

The evolution of our go-to-market model is attracting strong interest from third parties and this calendar year we have partnered with five pharma companies doubling our dermatology portfolio to 23 products. Partners include Upsher Smith, Torrent and Cosette and most recently we partnered with Chartwell Pharmaceuticals and launched a version of the acne brand TARGADOX® this week.

So far this fiscal year we have launched eight new dermatology products, one of which has become a top 3 US product by sales leveraging our established commercial capabilities across sales and marketing, medical affairs and patient access and support. In the first two months following launch, Mayne Pharma has captured 20% of the prescription volume with significant further growth expected across the balance of FY22. We are also in negotiations to launch another acne product shortly that participates in a US\$150m IQVIA market which is expected to be a meaningful contributor to our business based on current market conditions and competitor dynamics.

Today, our portfolio covers 9 of the top 15 most prescribed molecules by dermatologists. We continue to have active discussions with other parties around further product collaborations that will continue to add breadth to our offering on our path to ultimately becoming a one stop shop to satisfy the needs of dermatologists and patients alike.

### **Metrics Contract Services (Metrics or MCS)**

Metrics, our US contract service business continues to outperform market growth rates in the small molecule CDMO segment, benefiting from the growing number of oncology



compounds in clinical development, its diverse and high-quality customer base and the scientific know-how of its team of analytical chemists and formulators.

Metrics remains one of only a few US-based CDMOs capable of early-stage development through to commercialisation under a single FDA registration. Commercial manufacturing continues to make up a bigger proportion of its sales as more clients' transition from pre commercial development services to commercial phase. Metrics pipeline of development projects remains strong supporting more than 62 projects across the pharmaceutical value chain, up from 51 projects a year ago. We anticipate up to 5 of these clients may submit New Drug Applications with the FDA next year.

### International (MPI)

Our International business also known as MPI is one of Australia's leading specialty pharmaceutical and CDMO businesses. The Salisbury facility has expertise in complex oral and topical dose forms and the site manufactures and exports to more than a dozen countries. In Australia, MPI markets a portfolio of prescription and OTC products and out-licenses its products to third parties. The business is now actively focused on growing its CDMO services.

Our Australian commercial team are focused on building our dermatology and women's health portfolios. In July, we relaunched SOLARAZE® to treat actinic keratosis. We also anticipate approval of NEXTSTELLIS shortly with launch planned for mid-2022. Further, FABIOR® foam to treat acne is under active review at the TGA.

### Outlook

Mayne Pharma's success and performance will be heavily influenced by the execution of our strategic priorities and will depend on market factors including the timing of FDA approvals, payer coverage and reimbursement, and competitive intensity in our key product areas. We are focused on investing in activities that leverage and strengthen our core focus areas, namely women's health, dermatology and contract services.

Key growth drivers in the near to mid-term are expected to be the successful commercialisation of NEXTSTELLIS in the US, the launch of more than ten dermatology products this fiscal year, the launch of a generic version of NUVARING®, driving growth of Metrics Contract Services and continued optimisation of our cost base.

We have not provided a trading update today as year-to-date trading is not reflective of the expectations we have for the remainder of this half and the rest of the financial year, and we are not in a position to provide any guidance. Year to date trading has been mixed with Metrics Contract Services and International starting the year strongly whilst our US Products segments have had a softer start impacted by delays in launching key new products, one of which has now recently launched, and a number of one-off supply disruptions that are expected to reverse over the remainder of the year. There were no sales of NEXTSTELLIS in the period due to the inventory stocking in June 2021.

Finally, I would like to thank the leadership team and all our employees for their hard work and commitment to Mayne Pharma. I am confident we have the right strategies and operational plans to drive long term success for our company.

I will now hand back to Frank to complete the formal part of the meeting.

maynepharma

# Mayne Pharma Group Limited

Annual General Meeting  
9.00am (Melbourne time)  
23 November 2021

*Keeping our promises  
to patients, for  
**better medicines  
and a better  
tomorrow***



## Introduction



Frank Condella  
**Chair**



Ian Scholes  
**Deputy Chair**



Dr Carolyn Myers  
**Non-Executive Director**



Nancy Dolan  
**Non-Executive Director**



Scott Richards  
**CEO**



Peter Paltoglou  
**CFO**



Patrick Blake  
**Non-Executive Director**



Prof Bruce Robinson  
**Non-Executive Director**



## Agenda

1. Chair's Address
2. CEO's Address
3. Formal Business
4. Closing



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## Chair's Address

Frank Condella



# NEXTSTELLIS® contraceptive is our most significant growth opportunity



 **nextstellis®**  
(drospirenone and estetrol tablets)  
3 mg/14.2 mg

**\$25 Copay\*** for most eligible covered patients

**\$25\*** for most eligible uncovered patients

No activation required

BIN: 637765 PCN: CRX

GRP: TCPNEXT1

Member ID: XXXXXXXXXXXXX

 **mayne **pharma****

\*Restrictions and limitations apply. Please see reverse side for Terms, Conditions, and Eligibility Criteria.



## Our key strategic priorities

### Women's health

- Successful commercialisation of NEXTSTELLIS®
- Approval and successful launch of pipeline products pending at FDA (eg. gNUVARING®)
- Broaden women's health portfolio in areas of unmet need (eg. menopause, bacterial vaginosis, endometriosis)
- Maximise generic contraceptive portfolio

### Dermatology

- Broaden dermatology offering to patients and prescribers including launch of recently in-licensed products
- Continue to expand portfolio through business development activities, encompassing brand and generic business platforms
- Leverage brand and generic model to maximise total product portfolio

### US Contract Services

- Invest in broader capabilities (eg. high potent) and capacity to accelerate growth
- Deeper penetration of pre-commercial market across both formulation and analytical
- Expansion of commercial manufacturing and development client base in Greenville

### International

- Establish dermatology and women's health portfolios
- Advance pipeline for further growth domestically and internationally
- Expansion of contract development client base
- Establish new capabilities and capacity to accelerate growth of CDMO / CMO platforms

### Cost base

- Optimisation of supply chain to drive improved product costs (eg. API savings, manufacturing efficiencies)
- Optimisation of gross to net (eg. US WAC and copay card adjustments)
- Disciplined approach to investments in R&D, marketing and supporting systems and processes



- Reported revenue of A\$401m, down 12% (down 3% on constant currency)
- Reported EBITDA of A\$66m, down 14% (down 5% constant currency)
- Underlying EBITDA (excl. NEXTSTELLIS® set up costs) A\$75m (down 10% constant currency)
- Reported net loss after tax of A\$(208)m driven by asset impairments
- Metrics Contract Services and International delivered double digit gross profit growth in base currency
- Restructure of dermatology drove significant improvement in operating profitability of Specialty Products
- Generic Products impacted by competition on key products
- Positive operating cash flow of A\$59m
- Net debt reduced by A\$11m to A\$249m



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## CEO's Address

Scott Richards



## NEXTSTELLIS® launch continues to gain momentum

### *HCP engagement*

- >50,000 interactions with healthcare providers (HCPs) including >5,000 education lunches
- Sales team reached >6,000 HCPs and 70% of top prescriber targets
- NEXTSTELLIS® awareness amongst targeted HCPs is ~68% from a baseline of 2% at launch and ~48% have an intent to prescribe

### *Market access*

- Commercial coverage<sup>1</sup>: 67% formulary access, 55% unrestricted
- Medicaid: 94% formulary access, 34% unrestricted

### *Underlying demand*

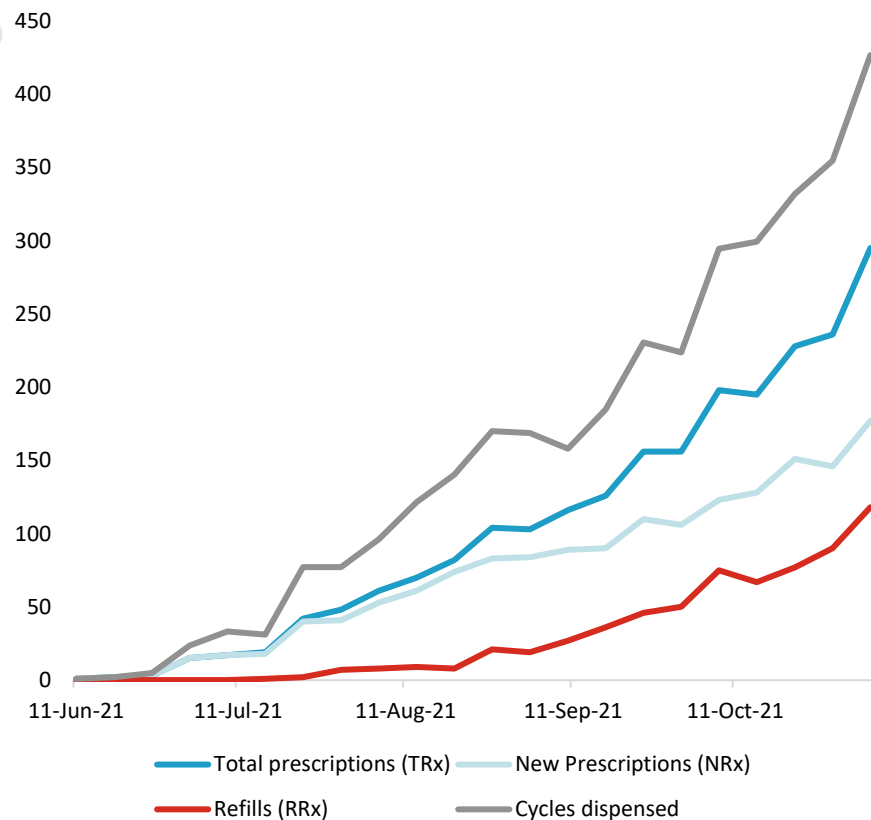
- >850 NEXTSTELLIS® writers
- >7,000 TRx written
- >3,000 TRx dispensed and >5,000 cycles since launch

<sup>1</sup>. Health insurance coverage of patient lives

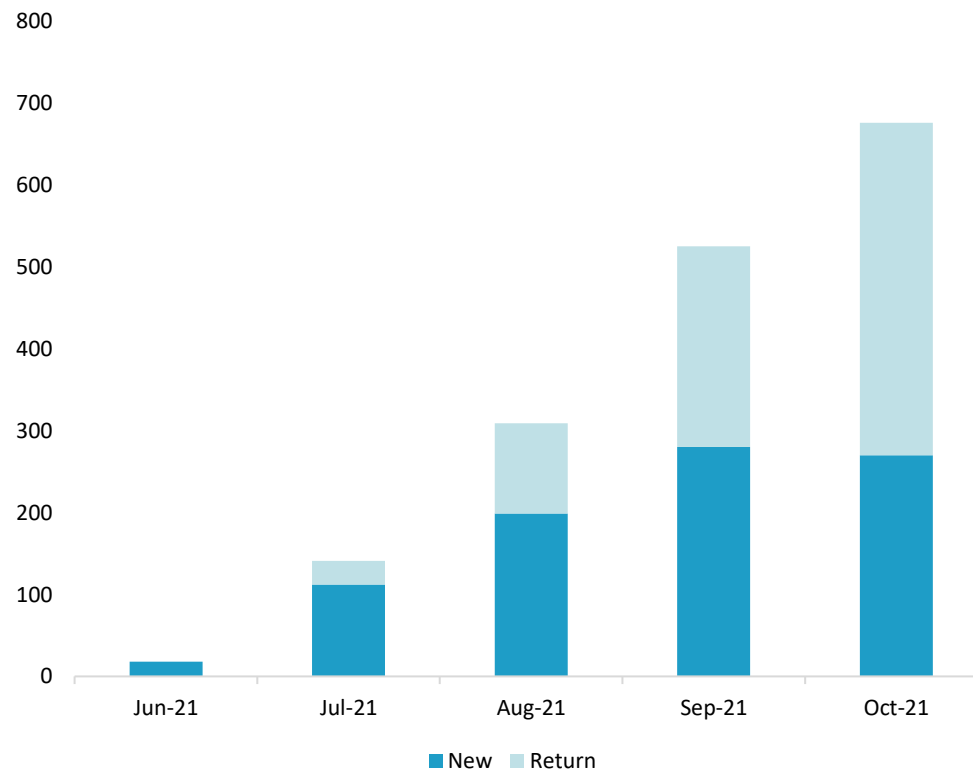


## NEXTSTELLIS® key performance metrics

NEXTSTELLIS® weekly performance metrics



NEXTSTELLIS® writers



# US pharma market themes / challenges



## Patient

- Rising costs
- Quality of insurance coverage



## Prescriber

- Less choice in patient treatment
- Greater administration



## Pharmacy

- Purchasing alliances
- Amazon and cash customers



## Manufacturer / Supplier

- Price deflation
- Reduced profitability and cashflow



## Wholesaler

- Purchasing alliances
- Amazon and direct to consumer



## Disruptors

GoodRx

MARK CUBAN  
COST PLUS  
DRUG COMPANY

PB GH Purchaser Business Group on Health

amazon pharmacy



## Payor/PBM

- Formulary blocks
- Increasing specialty drug costs