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

FORM 8-K

Current Report
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **November 9, 2022**

ANI PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-31812**	**58-2301143**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

210 Main Street West **Baudette, Minnesota**	**56623**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(218) 634-3500**

(Former name or former address, if changed since last report)

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

Title of each class:	**Trading Symbol(s)**	**Name of each exchange on which registered:**
Common Stock	ANIP	Nasdaq Stock Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

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

Item 2.02 Results of Operations and Financial Condition.

On November 9, 2022, ANI Pharmaceuticals, Inc. ("ANI") issued a press release announcing its financial and operating results for the three and nine months ended September 30, 2022. In connection with the press release, ANI held a telephone conference call on November 9, 2022. The full text of the transcript of the telephone conference call is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference in this Item 2.02.

The information furnished under this Item 2.02, including Exhibit 99.1, will not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, and will not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 7.01 Regulation FD Disclosure

The information in Item 2.02 is incorporated by reference.

The information furnished under this Item 7.01, including Exhibit 99.1, will not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, and will not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Cautionary Statement Regarding Forward-Looking Statements

To the extent any statements made in this Form 8-K deal with information that is not historical, these are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, those relating to the commercialization and potential sales of the product and any additional product launches from the Company's generic pipeline, other statements that are not historical in nature, particularly those that utilize terminology such as "anticipates," "will," "expects," "plans," "potential," "future," "believes," "intends," "continue," other words of similar meaning, derivations of such words and the use of future dates.

Uncertainties and risks may cause the Company's actual results to be materially different than those expressed in or implied by such forward-looking statements. Uncertainties and risks include, but are not limited to, the costs involved in commercializing Cortrophin, the ability to maintain regulatory approval of the product and maintain sufficiency of the product, the ability to obtain reimbursement from third-party payors for this product, evolving government legislation, the opinions and views of key opinion leaders and physicians who treat patients with chronic diseases and who may prescribe Cortrophin, ANI's ability to generate projected net product revenue and gain market share on the timeline expected, actions taken by competitors in response to a new market entrant; the ability of the Company to successfully maintain manufacturing capabilities and adequate commercial quantities of Cortrophin at acceptable costs and quality levels; broad acceptance of Cortrophin by physicians, patients and the healthcare community; the acceptance of pricing and placement of Cortrophin on payers' formularies; risks the Company may face with respect to importing raw materials and delays in delivery of raw materials and other ingredients and supplies necessary for the manufacture of our products from both domestic and overseas sources due to supply chain disruptions or for any other reason; the use of single source suppliers and the time it may take to validate and qualify another supplier, if necessary; manufacturing difficulties or delays, ANI's reliance on third parties over which it may not always have full control, increased competition and strategies employed by competitors; the ability to realize benefits anticipated from acquisitions, including but not limited to, the Oakrum product acquisition and post-close integration activities related to the Novitium acquisition; disruptions to our operations resulting from the ongoing shutdown and sale process relating to our Oakville, Ontario, manufacturing plant, including the transition of certain products manufactured there to our other facilities, or difficulties finding a buyer for the plant; costs and regulatory requirements relating to contract manufacturing arrangements; delays or failure in obtaining product approvals from the U.S. Food and Drug Administration; general business and economic conditions, including the ongoing impact of and uncertainties regarding the COVID-19 pandemic and inflationary pressures; market trends for our products; regulatory environment and changes; and regulatory and other approvals relating to product development and manufacturing, and other risks and uncertainties that are described in ANI's Annual Report on Form 10-K, quarterly reports on Form 10-Q, and other periodic reports filed with the Securities and Exchange Commission.

More detailed information on these and additional factors that could affect the Company's actual results are described in the Company's filings with the Securities and Exchange Commission (SEC), including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as other filings with the SEC. All forward-looking statements speak only as of the date hereof and are based on the Company's current beliefs, assumptions, and expectations. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

No.	Description
99.1	Transcript of Conference Call dated November 9, 2022
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded in the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ANI PHARMACEUTICALS, INC.

By: /s/ Stephen P. Carey
Stephen P. Carey
Senior Vice President Finance and Chief Financial Officer

Dated: November 9, 2022

Exhibit 99.1

ANI Pharmaceuticals, Inc.
November 9, 2022

Corporate Speakers

- Judy DiClemente; ANI Pharmaceuticals, Inc.; Investor Relations
- Nikhil Lalwani; ANI Pharmaceuticals, Inc.; President and Chief Executive Officer
- Steven Carey; ANI Pharmaceuticals, Inc.; Chief Financial Officer
- Christopher Mutz; ANI Pharmaceuticals, Inc.; Head of Rare Disease of ANI

Participants

- Elliot Wilbur; Raymond James; Analyst
- Brandon Folkes; Cantor Fitzgerald; Analyst
- Greg Fraser; Truist Securities; Analyst

PRESENTATION

Operator: Good morning, everyone. (Operator Instructions) At this time, I'd like to welcome everyone to ANI Pharmaceuticals Third Quarter 2022 Financial Results. (Operator Instructions) As a reminder, this conference call is being recorded today, November 9, 2022.

It is now my pleasure to turn the floor over to Ms. Judy DiClemente, Investor Relations for ANI Pharmaceuticals. Please go ahead.

Judy DiClemente: Thank you, Todd. Welcome to ANI Pharmaceuticals third quarter 2022 earnings results call. This is Judy DiClemente of In-Site Communications, Investor Relations for ANI. With me on today's call are Nikhil Lalwani, President and Chief Executive Officer; Steven Carey, Chief Financial Officer; and Christopher Mutz, Head of Rare Disease of ANI. You can also access the webcast of this call through the Investors section of the ANI website at anipharmaceuticals.com.

Before we get started, I'd like to remind everyone that any statements made on today's conference call that express a belief, expectation, projection, forecast, anticipation or intent regarding future events and the company's future performance may be considered forward-looking statements as defined by the Private Securities Litigation Reform Act. These forward-looking statements are based on information available to ANI Pharmaceuticals management as of today and involve risks and uncertainties, including those noted in our press release issued this morning and our filings with the SEC. Such forward-looking statements are not guarantees of future performance. Actual results may differ materially from those projected in the forward-looking statements. ANI specifically disclaims any intent or obligation to update these forward-looking statements, except as required by law. The archived webcast will be available for 30 days on our website, anipharmaceuticals.com.

For the benefit of those who may be listening to the replay or archived webcast, this call was held and recorded on November 9, 2022. Since then, ANI may have made announcements related to the topics discussed, so please reference the company's most recent press releases and SEC filings.

And with that, I'll turn the call over to Nikhil Lalwani. Nikhil?

Nikhil Lalwani:

Thank you, Judy. Good morning, everyone, and thank you for joining our call. Our financial results for the third quarter reflect the clarity of our Company's purpose to serve patients in need, alignment on our growth strategy and the dedicated focus on operational execution.

I am pleased to share that ANI delivered record net revenues of $83.8 million in the third quarter of 2022, achieving 61% year-over-year growth and 13% quarter-on-quarter growth.

Our non-GAAP EBITDA this year has increased from $4.3 million in Q1 to $9.9 million in Q2 to $19.6 million in the third quarter of 2022.

Over the past 12 months we have further strengthened the foundation of ANI with new capabilities and strategic initiatives to deliver sustainable growth:

- First, we have fully operationalized our integrated Rare Disease platform with medical affairs, market access, sales & marketing, patient support, specialty distribution and compliance infrastructure and capabilities.
- Second, a proven generics and 505 (b) (2) R&D engine further enabled with additional R&D investments towards niche limited competition pipeline products.
- And third, our ability to drive cost competitiveness by consolidating our manufacturing network through the closure of our facility in Oakville, Canada and consolidating distribution operations post acquisition with a 3rd party warehousing and logistics provider.

At this time, we are maintaining our guidance of 2022 total company revenues at $295 million to $315 million and adjusted total company non-GAAP EBITDA guidance at $54 million to $60 million.

Now, let me share details of the progress made across our key business lines.

For our Rare Disease Business Unit, building a successful Cortrophin Gel franchise remains our top priority. The Company achieved strong Cortrophin revenue growth, delivering $12.6 million in sales, up from $10.2 million in the second quarter. For those new to the ANI story, ANI launched Cortrophin earlier this year in January. Cortrophin is an NDA product that ANI acquired from Merck.

In terms of the launch trajectory, I am pleased to report that cumulative new patient cases initiated increased by greater than 50% to 765+ cases. We also continued to make further investments in our hub, patient support services and distribution network.

Physician interest in Cortrophin continues to build. The prescriber base increased by greater than 50% since our last report to 380 unique prescribers and, importantly, approximately one third of the prescribers have written more than one prescription. Prescriptions continue to be distributed across our targeted indications, which include certain chronic auto-immune disorders, including acute exacerbations of Multiple Sclerosis and Rheumatoid Arthritis, and excess urinary protein due to nephrotic syndrome.

We remain focused on market access and bringing savings to the healthcare system. Our efforts are paying off, as patients across Commercial, Medicare and Medicaid payers have access to Cortrophin.

We believe that with the addition of Cortrophin into the ACTH market, all stakeholders – namely, patients, prescribers, payers and pharmacy benefit managers – gain another treatment option. Most importantly, we continue to see evidence that our efforts are having a favorable impact on the overall number of patients receiving critical ACTH therapy.

Turning now to the other business segments...

Our 3Q generic revenues grew by 51% over the prior year quarter on the strength of our acquisition execution and success in bringing limited-competition drugs to market. We continue to invest in our generics and 505 (b) (2) R&D platforms to drive future growth. During the first nine months of 2022, we filed 11 ANDAs. In the third quarter, we also successfully launched multiple limited-competition products, including Prochlorperazine Maleate Tablets and Acebutolol Hydrochloride Capsules.

Our previously announced plan to consolidate manufacturing operations and cease operations at the Oakville, Ontario, Canada manufacturing facility in the first quarter of 2023 is on schedule. We have begun manufacturing many of the Oakville products in our U.S. facilities and are starting to see the benefits of the operational efficiencies from this initiative. As we complete this transition, we remain confident that our Baudette and New Jersey manufacturing sites can support our future growth and provide continuous service to customers and patients in need.

As part of this process, we are actively engaged and have made meaningful progress with a short list of potential buyers for Oakville. Once fully executed, this operational efficiency is expected to improve our profitability and cash flow by $7 million to $8 million on an annualized basis. Steve will have more to share on this shortly, but we currently expect one-time cash charges of approximately $2.7 million and non-cash charges of $4.4 million in conjunction with this action.

Business development is one of ANI's core strengths, and we continue to actively supplement our internal efforts when opportunities arise. As previously announced, we completed the acquisition of four limited-competition ANDAs from Oakrum Pharma. We expect to see the full impact of these product acquisitions in 2023.

In the established brands business unit, we continue to focus on efficiently promoting our key brands. We utilize a suite of commercialization techniques including tele-sales teams and ongoing patients support through copay assistance and patient starter samples. For our Dermatology portfolio, we have partnered with an established Dermatology company and expect our key Derm brands to return to growth on the back of these efforts. We are also actively evaluating business development deals to expand our portfolio of established brands.

Before I turn the call over to Steve, let me share an important recent addition to the ANI leadership team. I'd like to welcome Krista L. Davis, who joined ANI as Chief Human Resources Officer. Krista brings over 20 years of executive leadership experience in human resources, talent management, and organizational development, and will no doubt be an asset to the company as we grow and evolve into a leading biopharmaceutical company serving patients in need.

Steve will now walk through our detailed third-quarter financial results. Steve?

Thank you, Nikhil, and good morning to everyone on the call. My comments this morning will be focused on the three months ended September 30, 2022, versus prior year unless otherwise noted.

For the three months ended September 30, 2022, we posted total Net Revenues of $83.8 million, up $31.8 million, or 61%, as compared to the prior year period, driven by strong gains in both of our operating segments. Revenues for our Generics, Established Brands and Other segment were up $19.2 million, or 37%, over the prior year, while our Rare Disease Segment posted $12.6 million during the current year quarter.

Dollarized revenue gains were driven by Generic products and the 2022 launch of Purified Cortrophin Gel.

Net revenues for generic pharmaceutical products were $53.1 million during the third quarter of 2022, an increase of 51% compared to $35.1 million for the prior year period. The increase was principally driven by revenues from commercial generic products acquired in our acquisition of Novitium and revenues from multiple new product launches, partially tempered by a decrease in revenues from sales of several legacy ANI generic products.

Net revenues of rare disease pharmaceutical products, which consist entirely of sales of Purified Cortrophin Gel, were $12.6 million during the three months ended September 30, 2022. There were no sales of rare disease pharmaceutical products during the comparable prior year period.

Royalty and other revenues were $3.5 million in the current year quarter an increase of $3.3 million from the prior year, principally driven by licensing and royalty income related to Novitium products.

Contract manufacturing revenues were $4.8 million during the third quarter of 2022, more than double the $2.4 million posted in the prior year period, primarily related to the addition of Novitium contract manufacturing revenues.

Tempering the gains in the above categories were Net revenues for established brand pharmaceutical products, which were $9.8 million during the three months ended September 30, 2022. This represents a decrease of 31% compared to $14.3 million for the same period in 2021, driven by lower volumes of many of our brand products including Arimidex, Inderal LA, and Inderal XL.

Operating expenses increased by approximately 60% to $88.8 million for the three months ended September 30, 2022, from $55.6 million in the prior year period.

Cost of sales, excluding depreciation and amortization, increased by $8.5 million to $32.9 million in the third quarter of 2022 compared to $24.4 million in the prior year period, primarily due to increased sales volumes of generic products, including $6.5 million of costs of sales related to Novitium products during the current year period, with no comparable sales activity in the prior year, and an increase of $1.7 million related to increased sales of products subject to profit sharing arrangements.

Excluding the impact of acquisition accounting, stock compensation and the effects of our Oakville, Ontario plant closure, all of which are detailed in the tables contained in this morning's press release, Cost of Sales on a non-GAAP basis as a percentage of total adjusted Net Revenues decreased 4.4 points from 42.6% in the third quarter of 2021 to 38.2% in the current year period, primarily as a result of favorable mix from the impact of sales of Purified Cortrophin Gel coupled with increased 'Royalty and Other' revenues in the current year period. This decrease in cost of sale percentage was partially offset by lower sales of established brand products in the period.

Research and development expenses were $7.7 million in the third quarter of 2022, an increase of $5.2 million from the prior year period, primarily due to expenses related to Novitium generic research and development activities during the current year, with no comparable expenses in the prior year, coupled with in-process research and development charges of $1.2 million recognized in the current year period in conjunction with purchase accounting for our ANDA acquisition from Oakrum Pharm LLC.

Selling, general and administrative expenses increased by 75% to $30.1 million in the third quarter of 2022, compared to $17.2 million in the prior year quarter, primarily due to a $10.3 million increase in sales and marketing expenses related to our launch of Purified Cortrophin Gel, increased generic expenses primarily related to the addition of Novitium headcount and activities and tempered by a $0.4 million decrease in transaction expenses related to the Novitium acquisition.

Depreciation and amortization expense was $14.2 million for the three months ended September 30, 2022, compared to $11.3 million for the same period in 2021, an increase of $2.8 million, primarily due to the amortization of intangible assets acquired in the Novitium acquisition.

We recognized $1.5 million of restructuring expense in the third quarter of 2022, associated with the anticipated closure of our Oakville, Ontario, Canada facility. Costs included $0.4 million in termination benefits and $1.2 million in fixed asset impairment charges and accelerated depreciation. No restructuring activities were recognized in the prior year period.

We currently anticipate that we will incur another $0.6 million of severance related cash charges and another $1.9 to $2.4 million of non-cash accelerated depreciation over the course of the next two quarters. We have excluded both the one-time charges resulting from this action as well as the residual Canada results from our non-GAAP financial measures as detailed on tables in this morning's press release.

During the quarter ended September 30, 2022, we also recognized a non-cash fair value adjustment of $2.5 million related to the contingent consideration recorded in conjunction with Novitium purchase accounting. The expense is due to a reduction in the discount rate and the passage of time.

Our $(0.55) cent GAAP net loss per share for the quarter reflects significant amortization and purchase accounting related charges resulting from the Novitium acquisition coupled with the sales and marketing expense behind our initial commercial launch of Cortrophin and Oakville related restructuring activities. On an adjusted, non-GAAP basis, we had diluted earnings per share of $0.64 for the quarter, compared to $1.01 per share for the prior year period.

Adjusted non-GAAP EBITDA for the current year quarter of $19.6 million was up $3 million, or nearly 20% as compared to $16.6 million for the third quarter of 2021, and importantly on a sequential basis was up $9.7 million, or nearly double, as compared to the second quarter of this year.

From a cash and balance sheet perspective, the third quarter marked a return to positive cash flow from operations, with $3.6 million of cash provided by operations, after significant utilization of cash from operations in the first six months of the year as we invested behind the Cortrophin launch. During the quarter we also utilized over $7 million of cash in our acquisition of four ANDAs from Oakrum Pharma. As of the September 30th balance sheet date, the Company had $56.3 million in unrestricted cash and cash equivalents and $297.8 million in face value of outstanding debt which is due in November of 2027.

Finally, with this morning’s release, we are reiterating the following core elements of our full year 2022 guidance

- Total Company Net Revenue between $295.0 million and $315.0 million, representing approximately 36% to 46% growth as compared to $216.1 million recognized in 2021

- Cortrophin specific net revenue guidance between $40.0 million to $45.0 million

- Total Company Adjusted non-GAAP EBITDA between $54.0 million and $60.0 million, and

- Adjusted non-GAAP Diluted Earnings per Share between $1.34 and $1.62

We will now open up the call for questions. Operator, please go ahead with the instructions.

QUESTIONS AND ANSWERS

Operator: (Operator Instructions) We'll take our first question from Elliot Wilbur of Raymond James.

Elliot Wilbur: Thanks. Good morning. First question with respect to Cortrophin trends in the quarter Nikhil, thinking about the 50% increase in patient cases, initiated 50% plus increase in number of prescribers. Can you just sort of help us bridge those figures versus the actual sequential revenue change in the quarter which is, you know, roughly half that more around 25%. Understanding, obviously, you know, all patients weren't available for the entire period, but just trying to understand maybe what else may be occurring under the surface there.

And additionally, I want to ask a question on the number of prescribers that have written more than one prescription. You indicated last quarter, it was roughly a third or more than a third. I mean, this quarter, it's still more than a third. But help us think about, sort of persistence of therapy for patients who start if we're not seeing more meaningful improvement in terms of numbers, prescribers writing multiple Rx's. And I've got a couple of follow ups for Steve, but I'll stop there for the moment.

Nikhil Lalwani: And thank you, Elliot, and good morning. So the answer to your first question, we're pleased with the launch trajectory, increased physician interest in our product and expanded market access. And, you know, enrollment to fulfillment for Purified Cortrophin Gel is similar to other rare disease products, right? We continue to work closely with the PBMs and payers and invest in our hub and patient support infrastructure. As a result, we continue to see improvement in the new cases converting to patients on therapy. And then obviously, there's the details of that dynamic. That is, , that is responsible for the 50% increase in number of prescribers, 50% increase in the number of cases initiated, and that matching up with the launch numbers. So that's the answer to your first question.

And then the second question regarding 380 prescribers and persistence of therapies for existing patients. You know, why don't I let Chris, take that question?

Christopher Mutz: Yes, thanks. Thanks, Nikhil. You know, as you said, I think we're very encouraged by the increases we're seeing and new prescribers as well as repeat prescribers. I think the other piece is that we're still, we still have a lot of first physicians who are submitting their first prescription for Cortrophin. And so those that have started earlier in the cycle, maybe in 2Q and earlier in 3Q have the ability to then look for more patients to prescribe.

So, on an absolute basis, the number of repeat prescribers is increasing. So we're very encouraged by that for sure. But we'll continue to monitor that. We expect that to continue to increase, we're makinge headway into more and more prescribers and more -- and based on the positive reception we're getting.

I think from the standpoint of the patient mix and the persistence, we're really keeping a close eye on that, because we're really focused on three different target indications, and they have different -- I think, persistent treatment persistence curves, and we're continuing to look at that. But they are different based on the specialty and [inaudible].

Elliot Wilbur: Okay, thanks. And then just quickly for Steve, has there been any change in the original targeted investment spend, SG&A spend behind the Cortrophin asset this year, which I think was originally indicated, to be in the range of 42 million to 46 million, are you trending towards the higher end of that range, lower end or have you actually sort of changed that -- that metric? And then if you could just comment on gross margin trends, perhaps in the base generics business, revenue was better than ex -- or outperform the external expectations, but also look like it had a decent improvement in the margin profile of that portfolio as well, and just trying to tease out those numbers, but just want to get some more color there. Thanks.

Steve Carey: Yes. Thanks, Elliot. And good morning. Both very good questions. In terms of the Cortrophin Gel SG&A numbers, as you've probably noted, this morning, we reiterated the core revenue and profitability measures of our annual guidance. We did not specifically update the Cortrophin spend guidance, and that was intentional. You know, as we progress through the fourth quarter and make plans for 2023, we continue to focus on investing in key initiatives to drive future growth, right and set the franchise up for success in 2023.

And so as such, we're maintaining a degree of flexibility in those spend areas. Broadly speaking, we will be -- within our, -- close to the ranges that were previously put out, but again, we're maintaining flexibility to make strategic decisions as we invest into the business as the calendar turns to '23. As we're focused, as you would imagine, very focused on the mid and long-term success of the franchise.

On the second question, regarding the gross margins, I'll speak on it to the overall because we did have a very strong gross margin profile in the third quarter. And within that, I'll touch on the generics a bit as well.

If you look sequentially right, our non-GAAP adjusted gross margin was 61.1% in the third quarter which is up just a touch over seven points as compared to the second quarter of '22 and that improvement was driven by multiple factors.

First, favorable mix contributions from purified Cortrophin Gel and the established brands business on a sequential basis, favorable quarter-over-quarter royalty and license income thirdly, incremental revenues from off contract sales of select generic products due to market disruptions and that hones in on your point on the generic profile.

And then lastly, certain operational efficiencies that we've begun to realize due to the planned closure of our Oakville, Ontario manufacturing plants as we move products that were manufactured in Oakville into our other manufacturing facilities - we're gaining efficiencies in those go forward facilities so, really kind of good news in the quarter across multiple platforms, Elliot.

Elliot Wilbur: Okay, thank you.

Operator: Thank you. (Operator Instructions) We'll take our next question from Brandon Folkes of Cantor Fitzgerald.

Brandon Folkes: Hi, thanks for taking my questions and congratulations on the progress. Maybe just two from me on Cortrophin, and can you maybe focus on the market for Cortrophin? Are you seeing it grow year-on-year just (inaudible) report and decent numbers and you're putting up decent numbers here? Yes, it does seem that there may be actually the - an underlying growth in the market, but I'd love to get the commentary what you're seeing there.

And then just following on from the earlier question, can you just provide any color and maybe the number of vial per you're seeing in the sort of see 150 odd patients start so far or just remind us traditionally what your three target indications, what they have averaged? Thank you.

Nikhil Lalwani: Got it, yes thank you Brandon, and good morning. I'll let Chris answer the first question on overall market growth. And then I'll take the second one on a number of vials so Chris?

Christopher Mutz: Yes, thanks, Nikhil. Yes, so this is something we've been closely watching as we all know that there's been a significant decline in the overall market for the past number of years. And so, we've certainly seen the market stabilize and we have seen initial signs of growth. And we feel that is a very positive outcome of our launch and certainly a result of our - in part a result of our educational programming with physicians and the interactions we're having.

Nikhil Lalwani: Right, and just to build on what Chris just said, as you may have heard in the competitor's earnings call yesterday that they too have spoken about demand stabilization and it plays out in some of the data that's available in terms of PRXs. So most importantly, we're - from what we can see there are more patients beginning to benefit from ACTH therapy than the declining trend that we've been seeing in the past few years. And that is - aligned with what we had expected to happen.

And to your second question on number of vials per patient, our targeted indications continue to include certain chronic autoimmune disorders, including acute exacerbations of multiple sclerosis, rheumatoid arthritis, and excess urinary protein due to nephritic syndrome. So directionally the - what we see prescribers use from multiple sclerosis during an acute exacerbation, yes is lower than what we see in rheumatoid arthritis and nephrotic syndrome.

And obviously, that depends on the patient and the prescriber deciding how many vials to use per patient. But directionally for multiple sclerosis, you see lesser number of vials versus rheumatoid arthritis and nephrotic syndrome. And then in terms of further specificity throughout the initial launch period, we've sought to find balance between sharing information to assist the investment community while not giving away competitively sensitive data. So we appreciate your understanding on that Brandon and thank you for your questions.

Brandon Folkes: Understand. And thanks so much, and congratulations on the quarter.

Nikhil Lalwani: Thank you.

Operator: Thank you. We'll take our next question from Greg Fraser with Truist Securities.

Greg Fraser: Good morning, folks. Thanks for taking the question. For Cortrophin in the third quarter, can you talk maybe high level about how much of the growth was driven by new patients versus switches from ACTH? You noted that the prescriptions have been distributed across your targeted specialties. When do you plan to expand your promotional focus to other specialties that are big writers of ACTH or like pulmonology and ophthalmology.

Nikhil Lalwani: Got it. Good morning, and thank you, Greg, for your questions. Chris, you want to take the first one on new patients versus switches and then I'll take the second one on expanding focus.

Christopher Mutz: Yes, sure. So, in general, and we've talked about this before, our focus really isn't on the switch market necessarily. I mean, we're really educating around new patients starts. And so, you know, we think about our market in terms of new patients, and then refills, within a quarter. And so what we can say is that kind of month-over-month, quarter-over-quarter, the proportion of the refill contribution continues to grow. And this is exactly as we expected and modeled.

So, we're -- as we continue to have new patients, we benefit from the contribution of those new patients in each quarter, and we're showing steady progress there. But the benefit of the refills also is an important contributor.

Nikhil Lalwani: Yes, and to build on what Chris said, so our discussion with the prescribers is around finding the appropriate patients for our therapy, and not around switching from one therapy to another. So that's the first question.

And then second, look, I'm sorry for the general response. But throughout the launch period, we're trying to find balance, Greg as you will appreciate between sharing information to assess the investment community, while not giving competitively sensitive data. We are excited about the opportunities that lie ahead, both in the near term and in the midterm for Purified Cortrophin Gel, and there are multiple such opportunities. But we'll share more as we progress forward and thank you for your understanding.

Greg Fraser: I totally understand. Thanks for that. One more question on the generic business. Can you comment on base erosion and completion for new launches in the quarter? And for the full year, I guess, are you trending towards your prior expectation for base erosion in the higher single digit to low double-digit range? Or are you tracking ahead of that? Thank you.

Nikhil Lalwani: Yes, so I think the question base erosion versus new product launches, I think, as you'll see in our quarter-on-quarter, much as we plan, the erosion that we're seeing is made up for by the multiple limited competition, new product launches that we've done, so that, that strategy or approach of ours is to ensure that we're launching enough products to make up for the base erosion, you're seeing the growth quarter-on-quarter in our generics business, and we expect that to continue.

Then in terms, are we tracking overall below, you know, what we expected, I think that we're basically in line with the erosion that we had expected.

Greg Fraser: Thank you.

Nikhil Lalwani: Yes. Thank you, Greg.

Operator: Thank you. It appears that we have no further questions at this time. I will now turn the floor back over to Nikhil Lalwani for any additional or closing remarks.

Nikhil Lalwani: Thank you. Thank you, everyone for joining our call this morning. We are pleased with the progress made and remain focused on capturing the full potential of our lead rare disease product Cortrophin Gel, all while advancing our active generics and 505(b)(2) R&D engine, to continue delivering high quality medicines to those in need.

As always, we appreciate the support of our shareholders and look forward to sharing our future progress. Thank you again for joining our call and stay well.

Operator: This does conclude today's call. We thank you for your participation. You may disconnect at any time.